LAW ON HUMAN ORGAN TRANSPLANTATION FOR THE PURPOSE OF TREATMENT

I. GENERAL PROVISIONS

Article 1

(1) This Act determines the conditions for the transplantation of human organs and the safeguard of the quality and safety of human organs (hereinafter: organs) intended for transplantation for the purpose of treatment.

(2) This Act refers to the procedures of donating, obtaining, taking, testing, determining the characteristics of donors and organs, and the preservation, transport and transplantation of organs intended for treatment.

(3) The provisions of this Act shall not apply to reproductive organs, embryonic or fetal organs.

(4) Terms used in this Act and regulations adopted on the basis thereof, which have a gender meaning, regardless of whether they are used in the masculine or feminine gender, shall equally include the masculine and feminine genders.

Article 2

This Act contains provisions that are in line with the following acts of the European Union:

- Directive 2010/53 / EC of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 243, 16.9.2010),

- Commission Implementing Directive 2012/25 / EU of 9 October 2012 on the reporting of exchanges of human organs intended for transplantation between Member States (OJ L 275, 10.10.2012).

Article 3

(1) The procedures referred to in Article 1, paragraph 2 of this Act may be performed only in the manner and under the conditions determined by this Act.

(2) Any procedure related to the taking and transplantation of organs may be performed only if it is medically justified, or if it is the most favorable method of treatment.

Article 4

Terms in this Act have the following meaning:

1. *Donor* is a person who donates one or more organs, whether this donation takes place during life or after death,

2. *Donor characterization* is the process of collecting relevant data on the characteristics of a donor, needed to assess its acceptability for organ donation, in order to enable proper risk assessment and risk reduction for the recipient and effective organ allocation,

3. *Assessment of organ characteristics* is the process of gathering the relevant information on the characteristics of the organ, necessary to assess its acceptability, and to ensure an appropriate risk assessment and risk reduction for the recipient and the effective allocation of organs,

4. *Eurotransplant International Foundation* (hereinafter: Eurotransplant) is a non-profit European organ exchange organization, which deals with the allocation of organs at national and cross-border level, and most of its members are Member States of the European Union,

5. An *organ* is a differentiated part of the human body formed by different tissues, which retains its structure, vascularization and ability to develop physiological functions with a significant level of autonomy. A part of an organ is also considered an organ if its function is used for the same purpose as the whole organ in the human body, retaining the requirements of structure and vascularization,

6. *Donation* means the donation of organs for the purpose of transplantation,

7. *Procurement* is a set of organizational and professional procedures that enable the availability of organs for transplantation,

8. The *procurement system* applies to all health care institutions, hospital transplant coordinators / teams and the national coordinating body that undertake and / or coordinate procedures related to organ donation and procurement,

9. *Recovering* is a surgical procedure by which donated organs are recovered from the donor's body,

10. The *removal surgical team* is the expert team of the transplantation center that performs the taking of organs for the purpose of transplantation,

11. *Preservation* means the application of chemical agents, changes in environmental conditions or other means to prevent or slow down the biological or physical deterioration of organs from collection to transplantation,

12. A *serious adverse event* is any adverse and unexpected event related to any procedure in the process from donation to transplantation, which could lead to the transmission of a contagious disease, death or life-threatening condition, impotence and / or incapacity of the patient, or which could result in hospital treatment, illness or prolong such conditions,

13. A *serious adverse reaction* is an adverse reaction, including an infectious disease in a living donor or recipient, which may be associated with any procedure in the process from donation to human organ transplantation that causes death, is life-threatening, imposes impotence and / or incapacity, i.e., results in hospital treatment, illness or prolongs such conditions,

14. *Operating procedures* are written instructions describing the steps in a particular process, including the materials and methods used, and the expected end result,

15. *Transplantation* is a procedure intended to restore certain functions of the human body by transferring the organs of the donor to the recipient,

16. *Transplantation Center* is a clinical health institution, i.e., its organizational unit that performs organ transplantation, and has the approval of the Ministry for the activity of transplantation of individual or more organs,

17. *Transplantation program* means a set of organizational and professional procedures related to the implementation of transplantation of individual or a combination of several organs,

18. *Traceability* means the ability to locate and identify organs at any stage of the process from donation to transplantation or destruction, including the ability to:

a. identify the donor and explant team,

b. identify the recipient (s) in the transplant centers and

c. find and identify all significant, non-personal data on products and materials that come into contact with that body,

19. The *National Waiting List* is a database of persons - citizens of the Republic of Croatia who are waiting for an organ transplant,

20. *National Coordination Body* is an organizational unit of the Ministry responsible for monitoring the implementation of the National Transplant Program, and for the coordination of all activities related to organ donation and transplantation at the national and interstate level,

21. The *National Transplant Coordinator* is a medical doctor with experience in improving the transplant program, employed in the National Coordinating Body, and responsible for monitoring the implementation of the National Transplant Program and coordinating the work of hospital transplant coordinators, as well as international cooperation.

II. SOCIAL CARE FOR ENSURING THE ADEQUACY OF HUMAN ORGANS FOR THE PURPOSE OF TRANSPLANTATION

Article 5

In achieving social care for the health of its inhabitants throughout its territory, the Republic of Croatia ensures conditions for the promotion of organ donation, the achievement of quality and safety standards, and the adequacy of organs for transplantation.

Article 6

The Republic of Croatia fulfills its rights, obligations, tasks and goals in the field of organ donation and transplantation by:

- providing funds for the implementation of health-promoting, educational and other activities in the field of organ donation and transplantation,

- providing funds for organ procurement and transplantation procedures,

- establishing and ensuring an appropriate organizational model for the implementation of the National Transplant Program in the Republic of Croatia and for international cooperation.

National Transplant Program

Article 7

(1) Activities related to organ donation and transplantation shall be carried out in accordance with the National Transplant Program adopted by the Minister responsible for health (hereinafter: the Minister), at the proposal of the National Commission for Organ Transplantation for a period of four years.

(2) The National Organ Transplantation Commission (hereinafter: the Commission) shall be appointed by the Minister for a term of four years, and shall consist of representatives of transplantation programs, a national transplantation coordinator, a representative of hospital transplantation coordinators and a representative of an authorized immunogenetics laboratory.

(3) The Commission proposes professional guidelines, monitors and analyzes the success of transplantation programs, monitors the implementation of the National Transplantation Program, and proposes measures for its improvement, participates in planning and implementation of health-promoting and educational activities in the field of organ donation and transplantation.

(4) Healthcare institutions and healthcare workers, as well as the Commission referred to in paragraph 2 of this Article, shall be obliged to participate in the implementation of the National Transplant Program, in the manner prescribed by the Minister in an ordinance.

III. PROTECTION OF ORGAN DONORS AND RECIPIENTS, AND DONOR SELECTION AND EVALUATION

Principles of donating

Article 8

(1) It is prohibited to give or receive any monetary compensation for the taken organs, and to gain any other property benefit.

(2) The provision of paragraph 1 of this Article shall not apply to payments which do not represent monetary gain or comparable benefit, and in particular:

- compensation to living donors for lost earnings or any other eligible costs caused by organ harvesting or related to necessary medical examinations,

- reasonable compensation for necessary medical or technical services provided in connection with the transplantation,

- compensation in case of excessive damage resulting from the recovering of organs from a living donor.

Article 9

When removing organs from a deceased person, due regard shall be paid to the personal dignity of the deceased person and his or her family.

Organ allocation

Article 10

(1) The organs taken from a person must be transplanted in accordance with the rules of the medical profession.

(2) Organs shall be assigned considering their fair distribution and equal availability to recipients from the National Waiting List, in accordance with transparent, objective and generally accepted medical criteria.

(3) The manner of registration of recipients and keeping of the National Waiting List, as well as the criteria for assigning organs shall be prescribed by the Minister in an ordinance.

(4) As an exception to paragraph 2 of this Article, the allocation of organs within the framework of international exchange and membership in Eurotransplant shall be regulated by an international cooperation agreement.

(5) After the recovering and transplantation of organs to living donors and recipients, monitoring of their health condition shall be ensured.

Recovering organs from a living donor

Article 11

(1) The expert team of the transplant center and the ethics committee of the transplant center in which the transplant will be performed shall decide on the recovering of organs from a living donor for the purpose of transplantation to the recipient.

(2) As an exception to paragraph 1 of this Article, the decision of the ethics committee of the health institution is not required in the case of the recovering of an organ from a living related donor of the first line of blood relationship.

Article 12

(1) Before recovering organs, appropriate medical examinations and procedures must be carried out in order to assess and reduce the physical and mental risks to the health of the donor.

(2) The organ may not be recovered if there is a risk to the life or health of the donor.

(3) The manner and conditions of selection and assessment of the health condition of a living donor, the manner of its monitoring after transplantation, and the manner of keeping the Register of Donors shall be prescribed by the Minister in an ordinance.

Article 13

Organs may only be recovered from an adult, provided they are legally fit.

Article 14

Recovering an organ from a living donor is only allowed if the donor has given informed written consent for the procedure.

Article 15

(1) The informed consent of the organ donor must refer only to the planned procedure.

(2) Informed consent is given in writing and must be an expression of the donor's free will, based on appropriate information about the nature, purpose and course of the procedure, the likelihood of its success and the usual risks.

(3) Before giving informed consent, the donor should be informed of his rights prescribed by this Act, and in particular of the right to impartial advice regarding health risks from a doctor who will not participate in organ harvesting or transplantation, or who is not the recipient's personal physician.

(4) The donor may freely and at any time, until the beginning of the collection procedure, revoke his consent.

(5) The content and form of the consent form referred to in paragraph 1 of this Article and the content of the consent revocation form referred to in paragraph 4 of this Article shall be prescribed by the Minister in an ordinance.

Organ recovering from a deceased person

Article 16

(1) Organs from a deceased person may be recovered for transplantation to another person after the death has been determined with certainty, according to medical criteria and in the prescribed manner.

(2) The manner, procedure and medical criteria for determining the death of a person whose body parts may be taken for the purpose of transplantation shall be prescribed by the Minister in an ordinance.

(3) The death of a person whose body parts may be taken for transplantation shall be determined by a commission of a health institution composed of two doctors of medicine of appropriate specialties.

(4) A doctor of medicine who participates in the recovering or transplantation of organs from a deceased person or is responsible for the care of possible recipients of organs, may not participate in the work of the commission referred to in paragraph 3 of this Article.

Article 17

(1) Organs from a deceased person may be recovered for transplantation only if the donor has not objected to the donation in writing during his lifetime.

(2) The written statement referred to in paragraph 1 of this Article shall be given by an adult able-bodied person to the elected doctor of primary healthcare or to the Ministry competent for health (hereinafter: the Ministry).

(3) As an exception to the provision of paragraph 2 of this Article, for adults who are not legally capable, the written statement referred to in paragraph 1 of this Article, attested by a notary public, shall be given by the legal representative or guardian.

(4) A blind person, , a deaf person who cannot read and a deafblind person shall give the statement referred to in paragraph 1 of this Article in the form of a notary deed or a statement on the appointment of a capable person that will give a written statement.

Article 18

(1) The elected doctor of primary healthcare shall submit a written statement referred to in Article 17, paragraph 1 of this Act to the Ministry.

(2) The content of the form, the manner and procedure of delivery, the manner of keeping and checking the Register of Non-Donors, and the procedure of revoking the written statement referred to in Article 17, paragraph 1 of this Act shall be prescribed by the Minister in an ordinance.

(3) A person may revoke his written statement at any time.

(4) The written statement referred to in Article 17, paragraph 1 of this Act shall be stored at the Ministry, and the data from the statement shall be entered in the Register of Donors.

(5) Data on non-donors shall be kept in accordance with special regulations governing the protection of professional secrecy and the protection of personal data.

Article 19

Body parts of a deceased person who is not a citizen of the Republic of Croatia, i.e., does not have a permanent residence in the Republic of Croatia, may be taken for transplantation when a spouse or common-law partner, parent, adult brother, sister or adult child of the deceased agrees.

Article 20

Body parts of a deceased child and a deceased adult who was not legally capable may be taken for transplantation only if both parents agree in writing, if they are alive, or if his legal representative or guardian agrees.

Conditions of consent to transplantation

Article 21

(1) Organ transplantation may be performed only if the recipient has given written informed consent.

(2) The informed consent referred to in paragraph 1 of this Article must be an expression of the free will of the recipient, based on appropriate information on the nature, purpose and course of the intervention, the likelihood of its success and usual risks.

(3) For a recipient who is not legally capable or is a minor, the consent referred to in paragraph 1 of this Article shall be given by his legal representative or guardian.

(4) The content of the consent form referred to in paragraph 1 of this Article shall be prescribed by the Minister in an ordinance.

Protection of personal data, confidentiality and security of processing

Article 22

(1) Personal data on organ donors and recipients shall be a professional secret. Personal information about the deceased donor is not allowed to be given to the recipient, and personal information about the recipient is not allowed to be given to the family of the deceased donor.

(2) In the presence of a medically justified reason, the recipient's medical doctor must be provided with an insight into the donor's health data.

(3) Personal data referred to in paragraph 1 of this Article shall be collected, stored and communicated in accordance with the special regulations governing the protection of professional secrecy and the protection of personal data.

IV. QUALITY AND SAFETY OF BODIES

Quality and safety standards

Article 23

(1) All procedures referred to in Article 1, paragraph 2 of this Act must be carried out in accordance with the relevant professional obligations and standards, bioethical guidelines, and quality and safety standards.

(2) The standards of quality and safety referred to in paragraph 1 of this Article shall be prescribed by the Minister in an ordinance, and shall obligatorily include the application of operational procedures for:

- verification of the donor's identity,
- verification of appropriate consent,
- verification of the performed assessment of the characteristics of organs and donors,
- procurement, preservation, packaging and labeling of organs,
- organ transport,
- ensuring traceability,
- reporting and management of serious adverse events and serious adverse reactions,
- method of monitoring the health status of donors and recipients.

(3) All persons involved in the procedures referred to in Article 1, paragraph 2 of this Act must take all justified measures to reduce the risk of transmission of any disease to the recipient, and avoid any action that could affect the quality and safety of transplant organs.

Article 24

The assessment of the characteristics of the donor and the organ must be carried out before each organ transplant in the manner prescribed by the ordinance issued by the Minister.

Traceability

Article 25

(1) The Ministry and healthcare institutions participating in the procedures referred to in Article 1, paragraph 2 of this Act shall be obliged to keep documentation and ensure the traceability of all acquired, assigned and transplanted organs in the Republic of Croatia from donor to recipient and vice versa.

(2) The Ministry is obliged to ensure the application of a unique system for the identification of donors and recipients in order to enable the identification of donors and the finding of each body and recipient associated with it.

(3) The manner of recording and storing the data referred to in paragraphs 1 and 2 of this Article and the manner of reporting to other Member States of the European Union shall be prescribed by the Minister in an ordinance.

Transport of organs for transplantation

Article 26

The transport of transplant organs is performed under the conditions and in the manner prescribed by the ordinance issued by the Minister.

System for monitoring and reporting serious adverse events and serious adverse reactions

Article 27

(1) Healthcare institutions with approval for performing transplantation activities, as well as all institutions involved in the procedures referred to in Article 1, paragraph 2 of this Act, are obliged to establish an effective and verified system for monitoring and reporting serious adverse events and serious adverse reactions, for prompt notification and implementation of corrective measures and withdrawal from the use of organs and solutions that may cause a serious adverse event or a serious adverse reaction.

(2) The healthcare institution referred to in paragraph 1 of this Article shall be obliged to inform the Ministry and Eurotransplant in writing, without delay, of any serious adverse event and serious reaction, and to take all available measures to reduce the damage caused by any serious adverse event and serious adverse reaction and notify the Ministry in writing.

(3) The Ordinance on the manner of reporting on serious adverse events and serious adverse reactions, and on the manner of keeping records, deadlines and the manner of reporting to the bodies referred to in paragraph 2 of this Article and the Member States of the European Union is issued by the Minister.

(4) The Ministry is obliged to keep the Register of Serious Adverse Events and Serious Adverse Reactions referred to in paragraph 2 of this Article.

V. SYSTEM FOR PROCUREMENT, RECOVERING, TESTING AND TRANSPLANTATION OF ORGANS

Organ procurement

Article 28

(1) All hospital healthcare institutions are obliged to participate in the acquisition and preservation of transplant organs, including preparation, notification and optimal care of donors, and assessment of donor and organ characteristics in the manner prescribed by the ordinance issued by the Minister.

(2) The Minister, upon the proposal of the director of the hospital/health institution, shall appoint the hospital transplant coordinator and / or the coordination team (hereinafter: the coordinator).

(3) The coordinator shall organize and coordinate the work within the health institution, and cooperate with removal surgical teams and the national coordination body in order to carry out the activities referred to in paragraph 1 of this Article, and ensure maximum availability and safety of transplantation organs.

(4) In the case of international exchange of organs, the coordinator is obliged to ensure the transfer of information on the characteristics of the donor and the organ, in accordance with the communication operational procedure adopted by the Minister.

(5) The conditions regarding professional qualifications, as well as the rights and obligations of the coordinator / coordination team shall be prescribed by the Minister in an ordinance.

Organ transplantation

Article 29

(1) Organ transplantation may be performed only by a clinical health institution (hereinafter: transplantation center) which has been approved by the Minister to perform the activity of transplantation or recovering one or more organs.

(2) The Minister shall issue an approval for the performance of the activities referred to in paragraph 1 of this Article by a decision establishing that the transplantation center meets the conditions for performing the activities of transplantation.

(3) The approval referred to in paragraph 1 of this Article shall be issued by the Minister for a period of four years.

(4) The Minister shall issue a decision on revoking the approval referred to in paragraph 1 of this Article if he determines that the transplant center no longer meets the conditions prescribed by this Act and if the success of organ transplantation in the last two years is significantly below the Eurotransplant average.

(5) No appeal shall be allowed against the decision referred to in paragraph 1 of this Article, but an administrative dispute may be initiated.

(6) The conditions for performing transplantation activities in terms of space, workers, medical-technical equipment, quality and safety shall be prescribed by the Minister in an ordinance.

(7) The success of transplants referred to in paragraph 4 of this Article shall be monitored and analyzed in accordance with a special rulebook prescribed by the Minister.

Organ recovering

Article 30

(1) The removal of organs may be performed only by the removal surgical team of the transplantation center, which has been approved by the Minister to perform the activity of transplantation, i.e., the taking of one or more organs.

(2) The conditions regarding professional qualifications and the obligations of the removal surgical team shall be prescribed by the Minister in an ordinance referred to in Article 29, paragraph 6 of this Act.

Testing

Article 31

(1) Testing of donors for blood-borne diseases and immunogenetic testing of recipients and donors may be performed only by a laboratory to which the approval of the Minister has been given for the performance of that activity, in accordance with the provisions of this Act.

(2) Testing of donors may be performed in the manner and according to the conditions prescribed by the ordinance issued by the Minister.

VI. ORGAN EXCHANGE

Article 32

Healthcare institutions performing the activity referred to in Article 1, paragraph 2 of this Act shall cooperate with each other and with other bodies and organizations in the Republic of Croatia, as well as international bodies and / or European organ exchange organizations, in the manner prescribed by regulations issued by the Minister.

VII. NATIONAL COORDINATION BODY

Article 33

The Ministry, as the national coordinating body, monitors the implementation of the National Transplant Program and performs the following tasks:

1. provides 24 hours a day and 7 days a week an operating system for monitoring and coordinating the implementation of the National Transplant Program and international cooperation,

2. manages the central information system for the needs of the National Transplant Program,

3. issues approvals for organ recovering, testing and transplantation activities,

4. keeps the Register of Non-Donors,

5. maintains the National Register of Living Donors and the National Transplant Registry,

6. maintains the National Waiting List and monitors the allocation of organs in accordance with the established criteria,

7. keeps the Register of Serious Adverse Events and Serious Adverse Reactions,

8. coordinates the work of multidisciplinary teams, persons, healthcare institutions, institutions and organizations involved in the procedures of recovering, transplanting, testing, transport and exchange of transplant organs,

9. participates in the organization and provision of transport of teams and bodies,

10. coordinates and improves cooperation with related foreign and international organizations in order to exchange organs for transplantation,

11. plans, develops and participates in the implementation of educational and promotional programs, projects, action plans, guidelines, and strategic documents in order to improve the quality of the National Transplant Program and increase the number of donors.

VIII. SUPERVISION

Article 34

(1) Supervision over the application and execution of this Act and regulations adopted on the basis of this Act, as well as supervision over professional work in healthcare institutions performing the activity referred to in Article 1, paragraph 2 of this Act, shall be performed by the competent inspection authority of the Ministry.

(2) Regular inspections shall be carried out at least once every two years.

IX. MISDEMEANOR PROVISIONS

Article 35

(1) A fine of HRK 70,000.00 to HRK 100,000.00 shall be imposed on a legal person for a misdemeanor if:

1. acts contrary to Article 10 of this Act,

2. takes an organ from a living donor for the purpose of transplantation without a decision of the expert team and the ethics committee of the transplant center in which the transplant will be performed (Article 11),

3. does not perform appropriate medical examinations and procedures before taking the organ, i.e., if he takes the organ when there is a risk to the life or health of the donor (Article 12),

4. acts contrary to Article 13 of this Act,

5. perform organ transplantation without the written informed consent of the recipient, i.e., his / her legal representative or guardian (Article 21),

6. acts contrary to Article 23 of this Act,

7. fails to notify the Ministry, within the prescribed time limit, of a serious adverse event or serious adverse reaction (Article 27).

(2) A fine of HRK 5,000.00 to HRK 10,000.00 for the misdemeanor referred to in paragraph 1 of this Article shall also be imposed on the responsible person as the legal entity.

(3) A fine of HRK 5,000.00 to HRK 10,000.00 for the misdemeanor referred to in paragraph 1 of this Article shall also be imposed on a natural person.

(4) For the attempted misdemeanor referred to in paragraph 1, items 1 to 6 of this Article, the perpetrator shall be punished for the attempt.

X. TRANSITIONAL AND FINAL PROVISIONS

Article 36

The ordinances for the adoption of which he is authorized by this Act shall be adopted by the Minister within six months from the day this Act enters into force.

Article 37

Until the entry into force of the ordinance referred to in Article 36 of this Act, they shall remain in force, if they are not in conflict with this Act:

1. Ordinance on the manner of keeping medical records of the recovering and transplantation of parts of the human body (Official Gazette 152/05),

2. Ordinance on the content of the consent form for recipients of human body parts (Official Gazette 84/07),

3. Ordinance on the content of the consent form of a living donor of a human body (Official Gazette 84/07),

4. Ordinance on the manner of storing personal data of donors and recipients of human body parts for the purpose of treatment (Official Gazette 141/05),

5. Ordinance on data and the manner of keeping documentation on possible donors of human body parts for the purpose of transplantation from a deceased person (Official Gazette 188/03),

6. Ordinance on the criteria for the allocation of human body parts and the keeping of the national waiting list (Official Gazette 152/05 and 84/07),

7. Ordinance on the manner of storage and transport of parts of the human body intended for transplantation (Official Gazette 152/05),

8. Ordinance on measures to ensure the safety and quality of parts of the human body for medical use (Official Gazette 143/05 and 70/09),

9. Ordinance on the manner of cooperation with related foreign and international organizations for the purpose of exchanging organs or tissues for the purpose of transplantation (Official Gazette 141/05 and 44/07),

10. Ordinance on the content, manner and procedure of submitting the form and the manner of keeping records and the procedure for revoking statements on non-donation of body parts from a deceased person (Official Gazette 111/07),

11. Ordinance on the procedure for notifying the death of persons eligible as donors of parts of the human body due to transplantation for the purpose of treatment (Official Gazette 152/05),

12. Ordinance on the manner, procedure and medical criteria for determining the death of a person whose body parts may be taken for transplantation (Official Gazette 3/06),

13. Ordinance on the manner of work of coordinators in the procedures of recovering and transplanting body parts for the purpose of treatment (Official Gazette 51/06).

Article 38

Healthcare institutions that have been approved to perform the activities of recovering, transplanting and exchanging organs referred to in Article 27, paragraph 1 of the Act on Recovering and Transplanting Parts of the Human Body for the Purpose of Treatment (Official Gazette 177/04) and 45/09) are obliged to harmonize their work and operations with the provisions of this Act within one year from the day this Act enters into force.

Article 39

On the day, this Act enters into force, the Act on the Recovering and Transplantation of Parts of the Human Body for the Purpose of Treatment (Official Gazette 177/04 and 45/09) shall cease to be valid in the part relating to organs.

Article 40

This Act shall enter into force on the eighth day following that of its publication in the Official Gazette.

Class: 543-02 / 12-01 / 01

Zagreb, 14 December 2012

CROATIAN PARLIAMENT

OG 92/2016 (14.10.2016.), Ordinance on the manner of registration of recipients of organs and the manner of keeping the National Waiting List for organs and the criteria for organ allocation

THE MINISTRY OF HEALTH
1964
Pursuant to Article 10, paragraph 3 of the Transplantation of Human Organs for Medical Purposes Act (Official Gazette 144/12), the Minister of Health issues

RULES ON HOW TO REGISTER ORGAN RECIPIENTS AND HOW TO MAINTAIN THE NATIONAL LIST OF ORGANS AND THE CRITERIA FOR ALLOCATING ORGANS

Article 1

(1) This Ordinance regulates the manner of registering recipients of organs, the manner of keeping the National Waiting List (hereinafter: Waiting List) and the criteria for allocating organs for transplantation.
(2) Terms used in this Ordinance, which have a gender meaning, refer equally to the masculine and feminine genders.

I. MANNER OF REGISTERING THE RECIPIENT OF ORGANS TO THE NATIONAL WAITING LIST

Article 2

(1) Recipients of organs are patients, citizens of the Republic of Croatia, who have an indication for organ transplantation by the competent / selected transplant centre.
(2) Recipients of organs are registered on the Waiting List in the Republic of Croatia according to the same criteria, based on a positive decision of the Commission of the competent / selected transplant centre.

Article 3

(1) The possible recipient of an organ (hereinafter: the candidate) is a patient with terminal organ failure for whom treatment by organ transplantation is the method of choice.
(2) The indication for organ transplantation shall be determined by the competent physician of the appropriate specialty.

Article 4

(1) After the indication of each candidate referred to in Article 3 has been confirmed, it is necessary to process it in an appropriate manner for the purpose of applying to the Waiting List.
(2) The processing of candidates referred to in paragraph 1 of this Article shall be carried out in accordance with the standard operational procedure of the competent / selected transplantation centre on screening and pre-transplantation assessment of the recipient (hereinafter SOP).
(3) The SOP referred to in paragraph 2 of this Article must contain;
- indications for organ transplantation,
- processing procedure for the purpose of application to the Waiting List (set of mandatory searches and inspections),
- (in) eligibility criteria for applying to the Waiting List,
- the application procedure and the person responsible for applying for and renewing the candidate status on the Waiting List.
(4) Each transplant centre must have the SOP referred to in paragraph 2 of this Article available to the public and published on the website of the health institution.
(5) The SOP referred to in paragraph 2 of this Article must be harmonized with the national guidelines for organ transplantation and the Eurotransplant Manual referred to in Article 7, paragraph 2 of this Ordinance.

Article 5

(1) Any patient in the final stage of chronic kidney disease is a possible candidate for kidney transplantation of a deceased or living donor, if there is no absolute contraindication.

(2) Each candidate referred to in paragraph 1 of this Article shall be evaluated by a competent nephrologist in a timely manner (in the fourth or fifth stage of chronic kidney disease) for the possibility of kidney transplantation, as a method of elective renal replacement therapy.
(3) The evaluation of candidates referred to in paragraphs 1 of this Article shall be carried out in accordance with the SOP of the competent / selected transplant centre and the National Guidelines for Selection and Processing of Recipients and Kidney Donors, which are available on the Ministry of Health website wwwmiz.hr.

Article 6

(1) The final evaluation of the eligibility of candidates for organ transplantation and the Decision on the application of candidates for the Listing is made by the Commission of the competent / selected transplant centre.
(2) The Commission referred to in paragraph 1 of this Article shall consist of a transplant internist and a transplant surgeon / urologist.
(3) The decision referred to in paragraph 1 of this Article must be signed by both members of the Commission.

Article 7

(1) A candidate for the Eurotransplant List shall be registered by the competent transplant internist or another person authorized to remove the transplant centre, in the manner determined by the Eurotransplant Manual.
(2) The Eurotransplant Manual is a set of rules previously agreed on with the Eurotransplant Member States, related to the implementation of the transplantation program, which include guidelines for the management of the Waiting List, the criteria and the organ allocation system.
(3) The competent transplant internist or other authorized person referred to in paragraph 1 of this Article shall notify the candidate of the application to the Waiting List in writing and provide him with a printout of the Recipient Report from the Eurotransplant electronic database.

II. MANNER OF KEEPING THE NATIONAL WAITING LIST

Article 8

(1) The candidate personally and / or his / her competent physician shall be obliged to inform by telephone the competent transplant internist about any change in the candidate on the Waiting List's health condition, which temporarily or permanently disables the admission of organs, immediately upon learning of this change in status.
(2) The Transplant Center is obliged to regularly and timely update medical and other data and the status of the candidate on the Waiting List, in accordance with the rules prescribed by the Eurotransplant Manual.
(3) The candidate shall be removed from the Waiting List in the event of permanent inability to transplant, death or after the transplant has been performed.
(4) Each transplant centre is obliged to ensure lifelong monitoring of the health status of organ recipients and living organ donors by regular control examinations and entry of their general and medical data into national and Eurotransplant registers.

Article 9

The director of the healthcare institution where the transplant centre is located and the person / s authorized to register the candidate to the Waiting List in the transplant centre, are responsible for the authenticity of the general and medical data related to the application and the status of the candidate on the Waiting List and their timely renewal, referred to in Article 8, paragraph 4 of this Ordinance.

Article 10

Candidates for organ transplantation from living donors must be entered on the Waiting List according to the same criteria as recipients of organs from a deceased person.

III. CRITERIA FOR THE ALLOCATION OF ORGANS

Article 11

Candidates registered on the Waiting List are assigned organs according to the following criteria:
- medical criteria (depending on the authority, e.g. MELD),
- degree of urgency,
- immunogenetic criteria (degree of sensitization, tissue matching),
- waiting time,
- special circumstances (e.g. child, recipient of several organs),
- balance of organ exchange between Eurotransplant members, and other criteria set out in the Eurotransplant Manual and national guidelines for organ transplantation.

IV. TRANSITIONAL AND FINAL PROVISIONS

Article 12

Procedures for the registration of candidates to the Waiting List, initiated before the entry into force of this Ordinance, shall end with the provisions of the Ordinance on the criteria for the allocation of human body parts and the keeping of the national waiting list (Official Gazette 152/05 and 84/07).

Article 13

On the day, this Ordinance enters into force, the Ordinance on the criteria for the allocation of human body parts and the keeping of the national waiting list (Official Gazette 152/05 and 84/07) shall cease to be valid.

Article 14

This Ordinance shall enter into force on the eighth day following that of its publication in the Official Gazette.

Class: 011-02 / 16-04 / 30
Reg. No .: 534-02-1-2 / 2-16-02
Zagreb, 10 October 2016
Minister doc. dr. sc. Dario Nakić, MD, mp

MINISTRY OF HEALTH AND SOCIAL WELFARE

Pursuant to Article 21, paragraph 3 of the Act on the Taking and Transplantation of Parts of the Human Body for the Purpose of Treatment (Official Gazette 177/04), the Minister of Health and Social Welfare shall issue

RULES ON THE MANNER, PROCEDURE AND MEDICAL CRITERIA FOR DETERMINING THE DEATH OF A PERSON WHOSE BODY PARTS CAN BE TAKEN FOR TRANSPLANTATION

Article 1.

This Ordinance determines the manner, procedure and medical criteria for determining the death of a person whose body parts may be taken for transplantation.

Article 2

The death of a person from whom body parts are taken for transplantation will be considered to have occurred if that person has experienced a complete and final cessation of cerebral circulation (brain death).

Article 3

Brain death implies an irreversible disruption of the function of the brain, cerebellum and brainstem. The diagnosis is made on the basis of a clinical examination and is confirmed by one of the paraclinical confirmatory tests.

Article 4

The process of determining brain death can only begin if the following conditions are met:
- the etiology of irreversible brain damage is known and documented by CT findings (traumatic brain injury, spontaneous intracerebral hemorrhage, ischemic brain lesion, decompensated primary brain tumor, ischemic-anoxic brain damage and inflammation of the central nervous system),
- reversible causes that can mimic brain death are excluded: hypothermia below 35 ° C; hypotension with systolic blood pressure below 80 mmHg; metabolic and endocrine disorders (hepatic encephalopathy, hyperosmolar coma, preterminal uremia); intoxication with drugs from the group of neurodepressants, antiepileptics, anticholinergics and muscle relaxants; alcohol intoxication,
- the person has a clinical picture of apnea coma (no spontaneous breathing movements).

Article 5

Clinical examination determines the clinical signs of brain death:
1. absence of pupillary reaction to light,
2. absence of corneal reflex,
3. absence of reaction to painful stimulus in the area of nerve innervation n. trigeminal,
4. absence of oculocephalic reflexes,
5. absence of oculovestibular reflexes,
6. absence of pharyngeal reflex,
7. absence of tracheal reflex,
8. muscular atony,
9. atropine test,
10. Absence of spontaneous breathing on apnea test. After preoxygenation (100% O2 for 15 minutes), the patient is separated from the respirator, an oxygen catheter is placed in the endotracheal tube with an oxygen flow of 6 l / min, and an increase in pCO2 in the arterial blood to 60 mmHg is expected. The expected mean increase in pCO2 in the blood is 3 mmHg per minute, and the required time from taking the first arterial blood sample, i.e. the initial value of pCO2 to the

increase to 60 mmHg, can be calculated. The recommended initial value of pCO2 is 40 - 45 mmHg. If an attempt to breathe spontaneously is confirmed during the test, the criteria for diagnosing brain death are not met. If peripheral oxygen saturation falls below 85%, systolic blood pressure drops below 60 mmHg, and malignant arrhythmias occur, the test should be discontinued. Spinal reflexes may occur during the apnea test.
The apnea test is not performed during the second clinical examination if all the criteria for the diagnosis of brain death are met at the first examination.
The existence of spinal reflexes does not exclude determination of brain death.

Article 6

Brain death is determined by two consecutive clinical examinations. Between the first and second examination, which determine the complete cessation of brain function, there must be a prescribed minimum time interval of three hours for adults and children over 12 years of age, 12 hours for children between 2 and 12 years of age, and 24 hours for children between 2 months and 2 years of age.

Article 7

To determine brain death, it is mandatory to perform one of the following paraclinical confirmatory tests after a clinical examination:
1. selective panangiography of the brain,
2. transcranial Doppler sonography,
3. perfusion radionuclide scintigraphy,
4. evoked brain potentials,
5. EEG,
6. CT multislice contrast panangiography.
Technical standards for performing transcranial Doppler sonography are printed in Annex I to this Ordinance, of which it forms an integral part.
Technical standards for deriving evoked brain potentials are printed in Annex II. of this Ordinance, of which it forms an integral part.
Technical standards for EEG performance are printed in Annex III. of this Ordinance, of which it forms an integral part.

Article 8

Paraclinically confirmatory tests must be performed according to the rules of the profession that apply to brain death detection procedures.
To determine brain death, two EEG images without brain electrical activity for 20 minutes taken at equal intervals as well as a clinical examination are required.
It is sufficient to perform paraclinical confirmatory tests to determine complete cessation of cerebral circulation once.

Article 9

Clinical examination to determine brain death is performed by a committee composed of two doctors, as follows:
- for persons up to 12 years of age, anesthesiologist and pediatrician who works in the field of intensive care and has experience in the treatment of patients with severe brain injuries,
- for persons over 12 years of age, anesthesiologist and neurologist or neurosurgeon and anesthesiologist.

Article 10

The time of death of a person is taken as the time of determining the death of the brain, i.e. the signing of the form "Record of death determination" which is printed in Annex IV. of this Ordinance and of which it forms an integral part.

The record referred to in paragraph 1 of this Article shall be signed by specialist doctors who performed the clinical examination and a specialist doctor who performed paraclinical confirmatory tests to determine brain death.

Article 11

After determining brain death, the doctor must stop all further therapeutic procedures.
As an exception to the provision of paragraph 1 of this Article, under the conditions prescribed by law, it is permitted to continue medical procedures in the event that the deceased person is a donor of organs and tissues for transplantation.

Article 12

On the day this Ordinance enters into force, the provisions of the Ordinance on detailed medical criteria and the manner and procedure of determining the death of a person whose body parts may be taken for transplantation (Official Gazette 53/91) and the Ordinance on data and the manner of keeping documentation on potential donors of human body parts for transplantation from a deceased person (Official Gazette 188/03) and the Instructions for the Implementation of the Organ Explantation Program (Official Gazette 75/98) in the part relating to the manner, the procedure and medical criteria for determining the death of a person whose body parts may be taken for transplantation.

Article 13

This Ordinance shall enter into force on the eighth day following that of its publication in the Official Gazette.

Class: 011-02 / 05-01 / 10
Reg. No.: 534-06-05-1
Zagreb, 28 December 2005

Minister
doc. dr. sc. Neven Ljubičić, vr

ANNEX I

TECHNICAL STANDARDS FOR PERFORMING TRANSCRANIAL DOPPLER SONOGRAPHY IN THE DIAGNOSIS OF BRAIN DEATH

Doppler sonography (TCD): 2 examinations 30 minutes apart, 2MHz insonation through 3 windows, evidence of 3 vein reverberations to spikes and spectrum loss with maintained systemic pressure, extracranial same evidence in both ACC, ACI and both vertebral arteries.

ANNEX II

TECHNICAL STANDARDS FOR DERIVING EVOKED BRAIN POTENTIALS IN THE DIAGNOSIS OF BRAIN DEATH

Evoked potentials: SSEP: absence of N20-P22 bilateral, BAER: nonspecific
Somatosensory evoked potentials (SSEPs) obtained by median nerve stimulation are recorded. Special attention is paid to the derivation of component P14 (positive component that occurs approximately 14 ms after stimulation of the median nerve in the area of the radiocarpal joint, the occurrence of which is attributed to activity in the medial lemniscus). Fz-Pgz drainage is considered a

derivative that achieves the most reliable results regarding the distinction between coma and brain death, and is recommended for testing to confirm brain death. Fz-Pgz derivation registers the activity of the most fertile parts of the P14 generator (rP14), which is irreversibly lost with brain death and can be preserved in comatose patients. The N18 (N20) potential was described as long-term negativity widely distributed on the scalp, approximately 18–20 ms after n stimulation medianus at the level of the radiocarpal joint. The potential is registered via electrodes on the scalp above the parietal (Pz) or frontal cortex (Fz), with a reference electrode above the spinal medulla at the C2 level, and with the use of a non-cephalic reference electrode. N18 is generated in the nucleus cuneatus, the caudal part of the medulla oblongata near the respiratory center and is considered the best indicator of medulla oblongata function.

Auditory evoked potentials (BAER) are independent of the level of consciousness and the possible presence of strong analgesics or sedatives. The test is etiologically non-specific and must be analyzed in light of the findings of the clinical examination.

Potential generators are located in the statoacoustic nerve (components I-II) and the brainstem (components III-V). The potential is registered from the active electrodes to both ears or mastoids, with the reference electrode at Cz. The latency of individual components is of little importance in the diagnosis of brain death, and the presence of individual wave components is primarily analyzed. Progressive deterioration of auditory evoked potential findings indicates irreversible damage while a single abnormal finding may represent a reversible condition. The absence of components III-V combined with the completion of EEG activity registration is evidence of brain death.

ANNEX III

TECHNICAL STANDARDS FOR PERFORMING EEG IN THE DIAGNOSIS OF BRAIN DEATH

The state of electrical silence of the brain should be determined by the following methodology:

- use of at least 14 electrodes symmetrically arranged on the scalp according to the international system 10-20, so that all brain areas are explored (Fp2, F4, C4, T4, P4, O2; Fp1, F3, C3, T3, P3, O1);
- derivatives can be bipolar with a distance between electrodes of not less than 5 cm and / or monopolar (with reference biauricular electrodes);
- electrode impedance must be between 0.1 and 10 Kohm
- amplification must be 2microVolts / mm and calibration with positive or negative deflection of 5 mm for a signal of 10 microVolts;
- at least two-time constants (from 0.1 and 0.3 sec.) should be used during registration;
- during the recording, the reactivity to various forms of sensory stimulation on the electroencephalographic image (acoustic and nociceptive) should be determined successively;
- the duration of each electroencephalography registration must be at least 20 minutes;
- registration must be done on paper when determining the irreversible cessation of all brain functions.

ANNEX IV 1./3

Prilog IV.
1./3

naziv i adresa zdravstvene ustanove

ZAPISNIK O UTVRĐIVANJU SMRTI MOZGA

A: ime i prezime: _____

B: datum rođenja: ☐☐ ☐☐ ☐☐☐☐
dan mjesec godina

C: matični broj povijesti bolesti: _____

UVJETI ZA POČETAK POSTUPKA

D: datum: ☐☐ ☐☐ ☐☐☐☐
dan mjesec godina

E: dijagnoza: _____

F: oštećenje mozga: 1. uzrok _____

2. vrijeme pojave (ukoliko se može utvrditi):

3. oštećenje: ☐ primarno supratentorijsko ☐ sekundarno
☐ primarno infratentorijsko ☐ nije poznato

G: prisutni su slijedeći znakovi:	DA	NE	DA	NE
1. otrovanja	☐	☐	☐	☐
2. djelovanja lijekova (hipnotici, sedativi, neuroleptici) u dozama koje mogu utjecati na stanje svijesti	☐	☐	☐	☐
3. djelovanja mišićnih relaksansa	☐	☐	☐	☐
4. endogena depresija CNS	☐	☐	☐	☐
5. primarnog pothlađenja	☐	☐	☐	☐
6. endokrine ili metaboličke kome	☐	☐	☐	☐
7. cirkulacijskog šoka	☐	☐	☐	☐
	stupac ispunjava 1. član povjerenstva		stupac ispunjava 2. član povjerenstva	

ime i prezime članova povjerenstva: _____ _____

potpis i faksimil članova povjerenstva: ☐ ☐

ANNEX IV 2./3

Prilog IV.

2./3

PRVI PREGLED

H: datum i vrijeme: ☐☐ ☐☐ ☐☐☐☐ u ☐☐ ☐☐

dan mjesec godina sat min

I: UTVRĐENI SLIJEDEĆI KLINIČKI POKAZATELJI:

	DA	NE	DA	NE
1. Odsutnost reakcije zjenica na svjetlo	☐	☐	☐	☐
2. Odsutnost kornealnog refleksa	☐	☐	☐	☐
3. Odsutnost reakcije na bolni podražaj u području inervacije živca n.trigeminusa	☐	☐	☐	☐
4. Odsutnost okulocefalnih refleksa	☐	☐	☐	☐
5. Odsutnost okulovestibularnih refleksa	☐	☐	☐	☐
6. Odsutnost faringealnog refleksa	☐	☐	☐	☐
7. Odsutnost trahealnog refleksa	☐	☐	☐	☐
8. Atonija muskulature	☐	☐	☐	☐
9. Atropinski test	☐	☐	☐	☐
	stupac ispunjava 1. član Povjerenstva		stupac ispunjava 2. član povjerenstva	

J: smrt mozga klinički utvrđena ☐ DA

☐ NE

ime i prezime članova povjerenstva _____ _____

potpis i faksimil članova povjerenstva ☐ ☐

ANNEX IV 3./3

Prilog IV.

3./3

DRUGI PREGLED

K: datum i vrijeme: ☐☐ ☐☐ ☐☐☐☐ u ☐☐ ☐☐

dan mjesec godina sat min

L: UTVRĐENI SLIJEDEĆI KLINIČKI POKAZATELJI:

	DA	NE	DA	NE
1. Odsutnost reakcije zjenica na svjetlo	☐	☐	☐	☐
2. Odsutnost kornealnog refleksa	☐	☐	☐	☐
3. Odsutnost reakcije na bolni podražaj u području inervacije živca n.trigeminusa	☐	☐	☐	☐
4. Odsutnost okulocefalnih refleksa	☐	☐	☐	☐
5. Odsutnost okulovestibularnih refleksa	☐	☐	☐	☐
6. Odsutnost faringealnog refleksa	☐	☐	☐	☐
7. Odsutnost trahealnog refleksa	☐	☐	☐	☐
8. Atonija muskulature	☐	☐	☐	☐
9. Atropinski test	☐	☐	☐	☐
10. Odsutnost spontanog disanja pri apneja testu	☐	☐	☐	☐
	stupac ispunjava 1. član povjerenstva		stupac ispunjava 2. član povjerenstva	

ime i prezime članova povjerenstva: _____ _____

potpis i faksimil članova povjerenstva: ☐ ☐

M: paraklinički testom _____ potvrđena je smrt mozga.

navesti vrstu pretrage

datum i vrijeme: ☐☐ ☐☐ ☐☐☐☐ u ☐☐ ☐☐

dan mjesec godina sat min

ime i prezime liječnika: _____ potpis i faksimil: ☐

MINISTRY OF HEALTH

1108

Pursuant to Article 25, paragraph 3 of the Transplantation of Human Organs for Medical Purposes Act (Official Gazette 144/2012), the Minister of Health shall issue

RULES ON THE MANNER OF KEEPING MEDICAL DOCUMENTATION AND ENSURING THE TRACEABILITY OF ALL PROCURED, ALLOCATED AND TRANSPLANTED HUMAN ORGANS

Article 1

This Ordinance determines the manner of keeping medical and other documentation related to the procedures referred to in Article 1, paragraph 2 of the Human Organ Transplantation Act for the purpose of treatment (hereinafter: the Act), and ensuring the traceability of transplanted organs.

Article 2

This Ordinance transposes into the legal order of the Republic of Croatia Directive 2010/53 / EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 243, 16.9.2010).

Article 3

The provisions of the regulations on the protection of data secrecy shall apply to the collection, processing and exchange of personal data for keeping records in accordance with this Ordinance.

Article 4

(1) The Ministry of Health (hereinafter: the National Coordination Body) is responsible for the establishment, implementation and maintenance of the information system for keeping and monitoring the documentation referred to in Article 1 of this Ordinance in a manner that ensures accuracy, completeness, timeliness, transparency and traceability of all data. In addition to the procedures referred to in Article 1, paragraph 2 of the Act, the national coordination body is also responsible for data processing and preparation of reports for national and international institutions.

(2) The national coordination body is obliged to ensure the conditions for the smooth running and exchange of data, and to document the procedures referred to in paragraph 1 of this Article, regardless of the availability of the information system.

(3) The national coordination body shall be responsible for the compliance of the information system referred to in paragraph 1 of this Article with the applicable legal regulations.

Article 5

The national coordinating body is responsible for assigning a unique identification number to the donor and recipient of the organ.

Article 6

The national coordinating body implements and manages:

- List of Non-Donors,

- National Register of Living Donors,

- National Waiting List,

- National Transplant Registry, which includes records of all organ donors and recipients and enables monitoring and analysis of transplant outcomes (graft and patient survival),

- Register of serious adverse events and serious adverse reactions,

- Records on the allocation and exchange of organs in cooperation with the Eurotransplant International Foundation (hereinafter: Eurotransplant) in the manner defined by a special agreement between the National Coordination Body and Eurotransplant,

- Register of health institutions authorized for organ transplantation,

- other records related to the donation and transplantation of human organs.

Article 7

Healthcare institutions in which the procedures referred to in Article 1, paragraph 2 of the Act are carried out are obliged to keep documentation on the performance of the procedure within their competence and report to the National Coordination Body in the manner prescribed by this Ordinance.

Article 8

(1) Medical documentation on the taking of organs from living donors must contain:

- personal and health data of the donor,

- informed consent of the organ donor,

- the opinion of an independent doctor on the risk to the donor and the donor evaluation report,

- results of all laboratory and other donor assessment tests,

- the decision of the competent ethics committee on the acceptability of the donor,

- documentation on collection, which must contain data on the institution that performed the collection of organs from a living donor, data and signature of the person who performed the

collection, date and time of beginning and end of the performed collection and data on the taken human organ,

- personal and health data on the receiving patient to whom the organ will be transplanted,

- data on the health condition of the donor after organ harvesting.

(2) If the transplant center has not transplanted the organ for any reason, the transplant center is obliged to record the procedure of destruction of the human organ and the identification of persons responsible for the destruction and submit a copy of the destruction report to the National Coordination Body in no later than 2 days.

(3) The transplantation center is obliged to submit data on the health status of the living donor to the National Register of Living Donors in the manner prescribed by the instructions of the National Coordination Body.

(4) The transplantation center of the competent transplantation program shall be in charge of collecting and entering data in the Register referred to in paragraph 3 of this Article.

Article 9

(1) Medical documentation on the removal of organs from a deceased person must contain:

- record of determining the death,

- record of donor maintenance procedures,

- List of Non-Donor search report,

- blood group findings of the deceased and HLA typing,

- questionnaire on the assessment of the acceptability of organ (and tissue) donors,

- finding of laboratory and other tests,

- Donor Info form,

-documentation on collection, which must contain data on the authorized institution that performed the collection of organs, list of members of the explantation team and signature of the responsible person, date and time of beginning and end of the performed collection and data on the taken organ,

- certificate of takeover of organs,

- autopsy report, if performed,

- documentation on the reconstruction of the body,

- a report on the destruction of the organ with the stated reason for the destruction, if the taken organ has not been accepted for transplantation, in which the beginning and end of the destruction and the identification of the persons who carried out the destruction must be stated.

(2) A copy of the report on the destruction of organs shall be submitted by the hospital transplant coordinator (hereinafter: the coordinator) to the National Coordination Body no later than 2 days from the date of explantation.

(3) The data on the donor characteristics referred to in paragraph 1 of this Article (Donor info) shall be entered by the coordinator of the donor institution in the National Transplantation Register. One copy of the form (Donor info) is attached to the organ, and one copy is kept in the donor's documentation.

Article 10

Each organ taken must be accompanied by a completed form, the Report on the explanted organ, the appearance and content of which are set out in Annex I, which is printed with this Ordinance and forms an integral part of it.

Article 11

(1) The report on the explanted organ shall be filled in by the person who performed the explantation. One copy of the report is attached to the human organ taken, the other copy remains in the documentation of the authorized institution that performed the collection.

(2) The data from the Report on the explanted body referred to in paragraph 1 of this Article shall be submitted to the National Coordination Body immediately after the explantation.

Article 12

(1) Medical documentation on organ transplantation, from a living or dead donor, shall contain:

- informed consent of the recipient,

- information on entry on the waiting list,

- data on HLA typing and cross-reaction,

- Explanted organ report,

- Eurotransplant periallocation report,

- documentation on organ transplantation with data on the recipient, data on the institution that performed the organ collection, members of the transplant team, date and time of the beginning and end of transplantation and data on the quality of the organ that was transplanted,

- Report on organ transplantation,

- Periodic reports on the post-transplant course of the recipient, which must contain data on graft function, diagnosis - cause of graft failure, immunization and causes of immunization of the recipient and other data important for monitoring the post-transplant course and transplant outcome, including death of the recipient,

- data on monitoring the health status of the living donor,

- Report on (non) acceptance of organs for transplantation (in case when offered or taken over organs are not accepted for transplantation),

- Report on the destruction of organs with the stated reason for destruction, if the transplant has not been performed, in which the beginning and end of the destruction and the identification of the persons who carried out the destruction must be stated.

(2) The transplantation center is obliged to enter data on the recipient and organ transplantation in the National Transplantation Register. The transplant center of the competent transplant program is in charge of collecting and entering data into the National Transplant Registry.

(3) For each transplanted human organ, a completed form, report on organ transplantation, the appearance and content of which are set out in Annex II, which is an integral part of this Ordinance, must be attached.

(4) The report on organ transplantation shall be filled in by the person who performed the transplant. The data from the form shall be submitted in an appropriate manner to the National Coordinating Body immediately after the transplant has been performed, and no later than within 48 hours from the transplant.

(5) If the transplant center to which the organ has been assigned has not performed an organ transplant, it shall immediately notify the National Coordination Body and Eurotransplant by telephone and in writing, stating the reasons why the organ was not transplanted.

(6) If the organ taken for any reason will not be transplanted, the Transplant Center must document the procedure of destruction of the human organ and the identification of the persons responsible for the destruction. A copy of the report on the destruction of organs must be submitted to the National Coordinating Body no later than 2 days from the date of explantation.

Article 13

The national coordinating body is responsible for the timely delivery and exchange of data with Eurotransplant and other competent authorities of the Eurotransplant Member States with which it cooperates in the exchange of organs.

Article 14

(1) All health care institutions in which medical and other documentation related to the procedures referred to in Article 1, paragraph 2 of the Act have been created are obliged to keep the documentation for at least 30 years from the day of donation.

(2) The documentation referred to in paragraph 1 of this Article may also be kept in electronic form.

Article 15

On the day, this Ordinance enters into force, the provisions of the Ordinance on the manner of keeping medical records of the taking and transplantation of human body parts (Official Gazette 152/2005) shall cease to be valid.

Article 16

This Ordinance shall enter into force on the eighth day following that of its publication in the Official Gazette.

Class: 011-02 / 13-02 / 27

Reg. No.: 534-10-1-1-1 / 2-13-01

Zagreb, 10 April 2013

Minister
prof. dr. sc. Rajko Ostojić, Ph.D. med., vr

ANNEX I

1/3

REPORT ON EXPLANATED ORGAN - KIDNEY

naziv zdravstvene ustanove

broj donora

adresa zdravstvene ustanove

datum: ☐☐ ☐☐ ☐☐☐☐
dan mjesec godina

zdravstvena ustanova eksplantacijskog tima

A: eksplantacija ☐ monoorganska

☐ multiorganska

B: Podaci o donoru:

datum rođenja: ☐☐ ☐☐ ☐☐☐☐ spol: Ž M
dan mjesec godina

visina: ☐☐☐ težina: ☐☐☐ krvna grupa ☐ Rh ☐
cm kg

C: održavanje

heparin: _____ IU u ☐☐ ☐☐
sat min.

početak hladne perfuzije - aorta: ☐☐ ☐☐
sat min.

vrsta perfuzata: _____ volumen perfuzata: _____

cross clamp vrijeme: ☐☐ ☐☐
sat min.

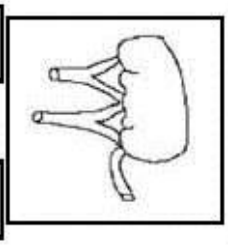
početak hladne perfuzije - v. Portae ili SMV: ☐☐ ☐☐
sat min.

D: Anatomija:

desni bubreg

broj arterija: _____ patch: DA NE
broj vena: _____ patch: DA NE
ureter _____ dug kratak

opaske:



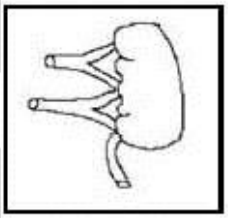
morfološke varijacije: DA NE

ako da, opisati:

lijevi bubreg

broj arterija: _____ patch: DA NE
broj vena: _____ patch: DA NE
ureter _____ dug kratak

opaske:



morfološke varijacije: DA NE

ako da, opisati:

E: Kakvoća:

desni bubreg

perfuzija: dobra prihvatljiva loša

nefrektomija u: ☐☐ sati

kakvoća desnog bubrega: dobar prihvatljiv loš

kirurg: _____
(ime i prezime)

potpis

lijevi bubreg

perfuzija: dobra prihvatljiva loša

nefrektomija u: ☐☐ sati

kakvoća desnog bubrega: dobar prihvatljiv loš

kirurg: _____
(ime i prezime)

potpis

ANNEX I

2/3

EXPLANATED ORGAN REPORT - LIVER / PANCREAS

naziv zdravstvene ustanove

broj donora

adresa zdravstvene ustanove

datum: ☐☐ ☐☐ ☐☐☐☐
dan mjesec godina

zdravstvena ustanova eksplantacijskog tima

A: Podaci o donoru:

datum rođenja: ☐☐ ☐☐ ☐☐☐☐ spol: Ž M
dan mjesec godina

visina: ☐☐☐ cm težina: ☐☐☐ kg krvna grupa ☐ Rh ☐

B: Održavanje:

heparin: _____ IU u ☐☐ sat ☐☐ min.

početak hladne perfuzije - aorta: ☐☐ sat ☐☐ min.

vrsta perfuzata: _____ volumen perfuzata: _____

cross clamp vrijeme: ☐☐ sat ☐☐ min.

početak hladne perfuzije - v. portae ili SMV: ☐☐ sat ☐☐ min.

C: Anatomija:

JETRA

normalna anatomija arterija: DA NE

ako ne, opisati: ☐

žučni mjehur pun	DA	NE
žučni vod pun	DA	NE
celijačna os	DA	NE
zajednička jetrena arterija:	DA	NE
SMA	DA	NE
aortalni patch	DA	NE
portalna vena	duga	kratka
kolecistektomija	DA	NE
iliačne arterije	DA	NE
ilijačne vene	DA	NE

GUŠTERAČA

cijeli / segment

s duodenumom / bez duodenuma

celijačna os	DA	NE
zajednička jetrena arterija:	DA	NE
SMA	DA	NE
aortalni patch	DA	NE
portalna vena	duga	kratka
kolecistektomija	DA	NE
iliačne arterije	DA	NE
ilijačne vene	DA	NE

D: Kakvoća:

jetra

perfuzija: dobra prihvatljiva loša

hepatektomija u: ☐☐ sati

kakvoća jetre: dobra prihvatljiva loša

kirurg: _____
(ime i prezime)

potpis: ☐

gušterača

perfuzija: dobra prihvatljiva loša

pankreatektomija u: ☐☐ sati

kakvoća gušterače: dobra prihvatljiva loša

kirurg: _____
(ime i prezime)

potpis: ☐

ANNEX I

3/3

EXPLANATED ORGAN REPORT - HEART-LUNG

naziv zdravstvene ustanove

broj donora

adresa zdravstvene ustanove

datum: ☐☐ ☐☐ ☐☐☐☐ (dan / mjesec / godina)

zdravstvena ustanova eksplantacijskog tima

A: Podaci o donoru:

datum rođenja: ☐☐ ☐☐ ☐☐☐☐ (dan / mjesec / godina)

spol: Ž M

visina: ☐☐☐ cm

težina: ☐☐☐ kg

krvna grupa ☐

Rh ☐

B: Održavanje:

SRCE

heparin: _____ IU u ☐☐ sat ☐☐ min

cross clamp vrijeme: ☐☐ sat ☐☐ min

početak hladne perfuzije: ☐☐ sat ☐☐ min

kardioplegična otopina(vrsta): _____

volumen perfuzata: _____ ml u _____ min

spremljeno u: kardioplegia drugo

PLUĆA SA SRCEM DA NE

PLUĆA

PGE1 (IV / RA / PA)

PGI2 (IV / RA / PA)

ostali lijekovi

otopina održavanja:

volumen perfuzata: _____ ml u _____ min

spremljeno u: otopina za održavanje drugo

inflacija: potpuna umjerena nema

masa pluća: _____ grama

PLUĆA U BLOKU DA NE

C: Kakvoća:

SRCE

perfuzija: dobra prihvatljiva loša

skleroza koronarnih arterija: LAD Cx RCA NEMA

kakvoća srca: dobra prihvatljiva loša

kirurg: _____ (ime i prezime)

potpis ☐

LIJEVO PLUĆE

perfuzija: dobra prihvatljiva loša

kakvoća : dobra prihvatljiva loša

_____ (kirurg: ime i prezime)

☐ potpis

DESNO PLUĆE

perfuzija: dobra prihvatljiva loša

kakvoća : dobra prihvatljiva loša

_____ (kirurg: ime i prezime)

☐ potpis

ANNEX II

1/4

ORGAN TRANSPLANTATION REPORT - HEART / LUNG

naziv zdravstvene ustanove

broj donora

adresa zdravstvene ustanove

A: datum transplantacije : ☐☐ dan ☐☐ mjesec ☐☐☐☐ godina

B: SRCE ☐

koronarna skleroza:

LAD	nema	prisutna	teška
CX	nema	prisutna	teška
RCA	nema	prisutna	teška

znakovi kontuzije: DA NE

PLUĆA ☐ LIJEVO ☐ DESNO

inflacija:	prekomjerna	☐	☐
	dobra	☐	☐
	loša	☐	☐
perfuzija:	homogena	☐	☐
	osrednja	☐	☐
	loša	☐	☐

atelektaze: gornji režanj DA NE DA NE

donji režanj DA NE DA NE

C: anatomski opis

lijevi atrij: otvoren intaktan

desni atrij: duljina SVC _____

duljina IVC _____

aorta, duljina: _____

plućna arterija, duljina: _____

anatomski opis

	LIJEVO	DESNO
atrijski cuff	DA NE	DA NE
aorta pričvršćena	DA	NE

D: vrijeme ishemije:

☐☐ sati ☐☐ min.

početna funkcija organa:

dobra ☐

osrednja ☐

loša ☐

vrijeme ishemije:

LIJEVO		DESNO	
☐☐ sati	☐☐ min.	☐☐ sati	☐☐ min.

početna funkcija organa:

	LIJEVO	DESNO
dobra	☐	☐
osrednja	☐	☐
loša	☐	☐
reperfuzijska ozljeda: nema	☐	☐
umjerena	☐	☐
teška	☐	☐

E: dodatne opaske:

transplantacijski kirurg:
(ime i prezime)

(potpis)

ANNEX II

2/4

ORGAN - KIDNEY TRANSPLANTATION REPORT

naziv zdravstvene ustanove

broj donora

adresa zdravstvene ustanove

A: datum transplantacije : ☐☐ dan ☐☐ mjesec ☐☐☐☐ godina

B: bubreg: ☐ lijevi ☐ desni ☐ en bloc

C: kakvoća čuvanja: ☐ dobra ☐ prihvatljiva ☐ loša

D: arterijski problemi:

E: venski problemi:

F: ureteralni problemi:

G: perfuzija: ☐ uredna ☐ mramorirana

H: ispunjeno izvješće o organu: ☐ DA ☐ NE

I: kakvoća parenhima:

J: trajanje: hladne ishemije: ☐☐ sat ☐☐ min. anastomoze: ☐☐☐ min

K: reperfuzijski tok: ☐ uredan ☐ smanjen ☐ odsutan
(ukoliko je učinjen prije operacije)

L: početna funkcija: ☐ dobra ☐ osrednja ☐ loša

M: boja poslije reperfuzije: ☐ ujednačena ☐ mramorna ☐ plava

N: konzistencija ☐ uredna ☐ tvrda ☐ napeta

O: dodatne opaske:

transplantacijski kirurg:

(ime i prezime)

(potpis)

ANNEX II

3/4

ORGAN - LIVER TRANSPLANTATION REPORT

naziv zdravstvene ustanove

broj donora

adresa zdravstvene ustanove

A: datum transplantacije : ☐☐ dan ☐☐ mjesec ☐☐☐☐ godina

B: jetra: ☐ cijela ☐ lijevi split ☐ desni split ☐ reducirana veličina

C: kakvoća čuvanja: ☐ dobra ☐ prihvatljiva ☐ loša

D: arterijski problemi:

E: venski problemi:

F: vena porte:

G: žučni vod:

H: perfuzija: ☐ uredna ☐ mramorirana

I: ispunjeno izvješće o eksplantiranom organu: ☐ DA ☐ NE

J: kakvoća parenhima:

K: trajanje: hladne ishemije: ☐☐ sat ☐☐ min. anastomoze: ☐☐☐ min

L: reperfuzijski tok: ☐ uredan ☐ smanjen ☐ odsutan
(ukoliko je učinjen prije operacije)

M: početna funkcija: ☐ dobra ☐ osrednja ☐ loša

N: boja poslije reperfuzije: ☐ ujednačena ☐ mramorna ☐ plava

O: konzistencija ☐ uredna ☐ tvrda ☐ napeta

P: dodatne opaske:

transplantacijski kirurg:

(ime i prezime)

(potpis)

ANNEX II

4/4

REPORT ON TRANSPLANTATION OF ORGANS - LIZARDS

naziv zdravstvene ustanove

broj donora

adresa zdravstvene ustanove

A: datum transplantacije : ☐☐ dan ☐☐ mjesec ☐☐☐☐ godina

B: bubreg: ☐ lijevi ☐ desni ☐ en bloc

C: kakvoća čuvanja: ☐ dobra ☐ prihvatljiva ☐ loša

D: arterijski problemi:

E: venski problemi:

F: duodenalni problemi:

G: perfuzija: ☐ uredna ☐ mramorirana

H: ispunjeno izvješće o eksplantiranom organu: ☐ DA ☐ NE

I: kakvoća parenhima:

J: trajanje: hladne ishemije: ☐☐ sati ☐☐ min. anastomoze: ☐☐☐ min

K: dodatne opaske:

transplantacijski kirurg:

(ime i prezime)

(potpis)

MINISTRY OF HEALTH

1109

Pursuant to Article 12, paragraph 3 of the Medical Organ Transplantation for Medical Purposes Act (Official Gazette 144/2012), the Minister of Health shall issue

RULES ON THE MANNER AND CONDITIONS OF SELECTION, ASSESSMENT AND MONITORING OF THE HEALTH CONDITION OF A LIVING ORGAN DONOR

Article 1

This Ordinance determines the manner, conditions of selection, assessment and monitoring of the health condition of a living organ donor, and the manner of keeping the donor register.

Article 2

This Ordinance transposes into the legal order of the Republic of Croatia Directive 2010/53 / EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 243, 16.9.2010).

Article 3

A living donor is a person who, on the basis of written informed consent as an expression of his or her free will, donates an organ or part of an organ to the recipient for the purpose of transplantation.

Article 4

The taking of organs from a living donor for the purpose of transplantation to the recipient must be done in a manner that poses the least physical and mental risk to the health of the donor.

Informing donors

Article 5

(1) Before taking an organ, the organ donor must be acquainted with:

- procedures and manner of assessing his health condition and eligibility for organ or partial organ donation,

- results and possible consequences of testing,

- the risks associated with the operation and the surgical procedure of organ harvesting, including the risk of death during the operation, as well as the possible impact on health and possible unpredictable consequences that may affect family and social life,

- personal responsibility and the possibility of exercising health insurance rights in case of a change of health condition, i.e. occurrence of disease

- the expected results of the transplant (desirable and undesirable) in the recipient and any specific conditions of the recipient that may influence his decision to donate organs.

(2) The donor must be informed of other available methods of treatment to the organ recipient.

(3) The donor must confirm that he fully understands the entire donation procedure and all information provided to him before giving written informed consent on organ donation.

Article 6

(1) The informing of the donor referred to in Article 5 of this Ordinance shall be carried out by a medical team composed of experts who do not participate in the treatment of the recipient.

(2) If the medical team referred to in paragraph 1 of this Article determines that organ harvesting poses a risk to the life or health of a living donor, who has given informed consent, the final decision on the eligibility of organ donors shall be made by the medical team.

Donor assessment

Article 7

(1) Before taking an organ, a complete medical and psychosocial assessment of the donor must be conducted by a multidisciplinary professional team that is trained and has the competencies to assess the eligibility of the person for organ donation.

(2) The donor's medical assessment must include medical history, behavioral and travel data with additional information from the selected primary care physician, clinical examinations and tests necessary to assess the acceptability of the donor and the organ being donated, and (if necessary) compatibility assessment with the recipient.

(3) The tests referred to in paragraph 2 of this Article shall be performed in accordance with special regulation.

(4) The assessment referred to in paragraph 1 of this Article shall also include an assessment of the physical and mental risks to the health of the donor, including the risk of exposure to the explant procedure and general anesthesia.

(5) The psychosocial assessment referred to in paragraph 1 of this Article must include an examination of the relationship between the potential donor and the recipient, an assessment of the psychological and social acceptability of the person for organ donation and the reason for the donation.

(6) All procedures and results of donor assessment shall be entered in the form printed in the Annex to this Ordinance and shall form an integral part thereof.

Article 8

The transplant center in which the organ donation was performed is obliged to provide:

- immediate postoperative monitoring and health care of the organ donor until his entire stay,

- long-term monitoring of the health condition and treatment of organ donors in the case of established pre-existing or acquired conditions not related to organ donation, which pose a health risk,

- cooperation with the selected doctor of primary health care in order to provide optimal care to the organ donor.

Article 9

The transplant center is required to provide procedures for reporting serious adverse reactions and serious adverse events (e.g., need for dialysis or organ transplantation, death) for the purpose of monitoring living donors.

Article 10

(1) Immediately after the donation of an organ, the transplant center is obliged to register the living donor in the National Register of Living Donors and to ensure its regular and lifelong monitoring.

(2) The transplant center is obliged to provide regular preventive examinations of the donor, at least once a year.

(3) Data on the health status of donors must be entered in the National Register of Living Donors for the purpose of quality control of transplant outcomes.

(4) Data from the National Register of Living Donors shall be kept in accordance with special regulations governing the protection of professional secrets and the protection of personal data.

(5) Data from the National Register of Living Donors may be processed collectively for the purposes of analysis of results and for scientific purposes.

Article 11

This Ordinance shall enter into force on the eighth day following that of its publication in the Official Gazette.

Class: 011-02 / 13-02 / 42

Reg. No .: 534-10-1-1 / 1-13-1

Zagreb, 11 April 2013

Minister

prof. dr. sc. Rajko Ostojić, Ph.D. med., vr

ANNEX

Assessment of a living organ donor

INFO ON THE DONOR/ TYPE OF ORGAN	
Name and surname of the donor	
Date of Birth	
Sex	
Reason for donating	
Identification number	
Organ	

INFO ON THE RECIPIENT	
Identification number	
Date of birth	
Sex	

RELATIONSHIP BETWEEN DONOR AND RECIPIENT
• Mother/father • Sibling • Child • Member of the extended family • Spouse/ Partner • Donor is an indipendent donor

LABORATORY FINDINGS	DATE

TEST	DATE

CLINICAL EXAMS	DATE

IMMUNOLOGICAL TESTS	DATE

MINISTRY OF HEALTH

1110

Pursuant to Article 27, paragraph 3 of the Transplantation of Human Organs for Medical Purposes Act (Official Gazette 144/2012), the Minister of Health shall issue

RULES ON THE MANNER OF REPORTING, THE MANNER OF KEEPING RECORDS AND DEADLINES FOR REPORTING ON SERIOUS HARMFUL EVENTS AND SERIOUS HARMFUL REACTIONS IN TRANSPLANTATION PROCEDURES

Article 1

This Ordinance prescribes the manner of reporting on serious adverse events and serious adverse reactions and the manner of keeping records and deadlines for reporting on serious adverse events and serious adverse reactions related to procedures from donation to transplantation of human organs for medical purposes.

Article 2

This Ordinance transposes the following directives into the legal order of the Republic of Croatia:

- Directive 2010/53 / EC of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 243, 16.9.2010),

- Commission Implementing Directive 2012/25 / EU of 9 October 2012 on the reporting of the exchange of human organs intended for transplantation between Member States (OJ L 275, 10.10.2012)

Article 3

Transplantation centers and all health care institutions involved in procedures from donation to transplantation of human organs for the purpose of treatment are obliged to appoint a person / s in charge of monitoring and reporting serious adverse events and serious adverse reactions and notify the Ministry of Health (hereinafter: National Coordinating Body).

Article 4

(1) All healthcare professionals involved in the procedures referred to in Article 3 of this Ordinance shall notify the appointed person in the healthcare institution of any serious adverse reaction or serious adverse event or suspicion of a serious adverse reaction or serious adverse event requiring urgent action, by telephone, without delays.

(2) The designated person is obliged to inform the National Coordinating Body and the Eurotransplant International Foundation (hereinafter referred to as: Eurotransplant) of any serious adverse reaction or serious adverse event or suspicion of a serious adverse reaction or serious adverse event requiring urgent action to avoid endangering public health, by telephone and in writing.

(3) The national coordinating body shall, in cooperation with Eurotransplant, without delay notify the competent authorities of the countries in which the transplant centers of the recipient organs are located and all transplant centers receiving organs, of a serious adverse event and / or serious adverse reaction or suspicion of a serious adverse event and / or a serious adverse reaction referred to in paragraph 2 of this Article, in the manner prescribed by the form in Annex I, which is an integral part of this Ordinance.

(4) The transplantation center or health institution shall submit all available information and perform a risk assessment and an assessment of the possible causal link between the taking or transplantation of organs or other procedures referred to in Article 3 of this Ordinance and a serious adverse reaction or serious adverse event. Upon completion of the research, the transplantation center shall submit a conclusion to the National Coordinating Body.

(5) The national coordinating body shall, within three months from the submission of the initial report referred to in paragraph 3 of this Article, submit to Eurotransplant and the competent authorities of the countries where the organ transplant centers are located, a final report on a serious adverse event or serious adverse reaction, containing the information listed in Annex II. which is an integral part of this Ordinance.

Article 5

In the event of the reception of a notification of a serious adverse reaction or a serious adverse event or suspected serious adverse reaction or serious adverse event from Eurotransplant Member States or other countries, the National Coordinating Body shall without delay inform the designated person of the organ transplant center and, through cooperation, ensure the implementation of preventive and corrective measures by the transplant center.

Article 6

(1) In addition to the procedures referred to in Articles 4 and 5 of this Ordinance, the National Coordinating Body shall participate in the international system of the European Union for the urgent reporting and reporting of serious adverse reactions and serious adverse events.

(2) The national coordinating body shall prepare and submit an annual report on the reported serious adverse events and serious adverse reactions to the European Commission no later than 30 June of the current year for the previous year.

Article 7

This Ordinance shall enter into force on the eighth day following that of its publication in the Official Gazette.

Class: 011-02 / 13-02 / 41

Reg. No.: 534-10-1-13-2

Zagreb, 9 April 2013

Minister

prof. dr. sc. Rajko

Ostojić, Ph.D.
med., vr

ANNEX I

INITIAL REPORT ON SUSPICION OF SERIOUS HARMFUL EVENT AND / OR SERIOUS HARMFUL REACTION (OŠDR / O)

Health institution		
Croatian identification number of the initial report		
Organ donor identification number		
Date and time of the occurrence of the harmful event and/or serious harmful reaction		
Date and time of the discovery of the harmful event and/or serious harmful reaction		
Date of application		
Transplant center(s) and State(s) in which the organ was transplanted		
1.		
2.		
3.		
...		

Identification number of the recipient of the organ

	ET Number	Croatian Number
1.		
2.		
3.		
...		

A description of the serious adverse event and/or serious adverse reaction

Immediate measures taken/proposed

Name and surname of the applicant

Signature

Date

ANNEX II

FINAL REPORT ON SERIOUS HARMFUL EVENT AND / OR SERIOUS HARMFUL REACTION

Croatian identification number of the initial report
Date and time of the presentation of the report
Case description

Other Member States involved	1. 2. 3. 4.
Research result	
Preventive and corrective measures taken	
Conclusion/follow-up, if necessary	
Name and surname of the person responsible Signature	
Date	

MINISTRY OF HEALTH

1111

Pursuant to Article 46, paragraph 3 and Article 47, paragraph 2 of the Act on the Application of Human Tissues and Cells (Official Gazette 144/2012), the Minister of Health shall issue

RULES ON THE MANNER OF MONITORING SERIOUS HARMFUL EVENTS AND SERIOUS HARMFUL REACTIONS IN THE FIELD OF TRANSPLANTATION OF HUMAN TISSUES AND CELLS, THE MANNER OF KEEPING RECORDS AND REPORTING DEADLINES

Article 1

(1) This Ordinance prescribes the manner of monitoring serious adverse events and serious adverse reactions in the field of transplantation of human tissues and cells, the manner of keeping records and deadlines for reporting to the Ministry of Health (hereinafter: the Ministry) on serious adverse events and serious adverse reactions, the content and form of the form of the annual report on the activities of the tissue bank or laboratory.

(2) A health care institution that performs the activity of collecting and taking tissues and cells (hereinafter: tissues) from living donors is obliged to establish procedures for keeping documentation on collected tissues.

(3) The health institution that performs the activity of tissue application is obliged to establish procedures for keeping documentation on applied tissues.

Article 2

This Ordinance transposes the following directives into the legal order of the Republic of Croatia:

- Directive 2004/23 / EC of the European Parliament and of the Council of 31 March 2004 laying down quality and safety standards for the donation, procurement, testing, treatment, storage, storage and distribution of tissues and cells of human origin (OJ 2004 L 102, 7. April 2004),

- Commission Directive 2006/86 / EC of 24 October 2006 implementing Directive 2004/23 / EC of the European Parliament and of the Council as regards monitoring requirements, the reporting of serious adverse reactions and occurrences and certain technical requirements relating to labeling, treatment, storage, storage and distribution of tissues and cells of human origin (Text with EEA relevance) (OJ L 294, 25.10.2006).

REPORTING SERIOUS ADVERSE REACTIONS

Article 3

(1) A health care institution that performs the activity of collecting and taking tissue from living donors is obliged to establish procedures for notifying the tissue bank, and the Ministry, of serious adverse reactions.

(2) The health institution referred to in paragraph 1 of this Article shall without delay report to the tissue bank, and the Ministry, any serious adverse reaction or suspicion of a serious adverse reaction

that occurred in living donors during or after tissue donation, which may affect the quality and acceptability of tissue for transplantation.

Article 4

(1) The health care institution in which the activity of tissue application is performed is obliged to establish procedures for notifying the tissue bank and the Ministry of serious adverse reactions.

(2) The health care institution referred to in paragraph 1 of this Article shall without delay report to the tissue bank and the Ministry any serious adverse reaction or suspicion of a serious adverse reaction observed in the tissue recipient during or after application, which may be related to tissue quality and safety.

Article 5

(1) Tissue banks are obliged to submit detailed written instructions on the manner of reporting serious adverse reactions referred to in Articles 3 and 4 of this Ordinance to health care institutions that perform the activity of collecting, taking and applying tissue.

(2) The notification of serious adverse reactions must contain the data and be submitted on Form I. A, which is printed in Annex I to this Ordinance and forms an integral part thereof.

Article 6

(1) The tissue bank is obliged to establish procedures for notifying the Ministry of serious adverse reactions and of the conclusions of the investigation of serious adverse reactions.

(2) The tissue bank shall be obliged to notify of any serious adverse reactions or suspicions of serious adverse reactions referred to in Article 3 and Article 4 of this Ordinance:

- inform the Ministry without delay and submit all available information,

- perform a cause-and-effect relationship analysis

- without delay, upon completion of the research, submit a conclusion to the Ministry.

(3) The conclusion must contain information and be submitted on Form I. B, which is printed in Annex I to this Ordinance and forms an integral part thereof.

(4) The tissue bank shall be obliged to inform the Ministry of the measures taken in relation to other tissues distributed for application, which may be affected by the cause of the reported serious adverse reaction.

Article 7

(1) Tissue banks are obliged to keep records of serious adverse reactions, research conclusions and measures taken.

(2) Tissue banks are obliged to submit to the Ministry an annual report on serious adverse reactions for the previous year by 1 March of the current year.

(3) The report referred to in paragraph 2 of this Article must contain data and be submitted on Form III. A, which is printed in Annex III. of this Ordinance and forms an integral part thereof. The annual report on serious adverse reactions must also be submitted in electronic form.

REPORTING SERIOUS HARMFUL EVENTS

Article 8

(1) Health care institutions in which the activities of collecting, taking and applying tissues are performed, are obliged to establish procedures for informing the tissue bank, and the Ministry, about serious harmful events.

(2) The health care institution referred to in paragraph 1 of this Article shall be obliged to report to the tissue bank, and the Ministry, without delay, any serious adverse event or suspicion thereof that may affect the quality and safety of the tissue.

Article 9

(1) Tissue banks are obliged to submit detailed written instructions to health care institutions for the collection, taking and application of tissue, on the manner of reporting a serious adverse event referred to in Article 8 of this Ordinance.

(2) The application referred to in paragraph 1 of this Article must contain data and be submitted on Form II. A, which is printed in Annex II. of this Ordinance and forms an integral part thereof.

Article 10

(1) The tissue bank is obliged to establish procedures for notifying the Ministry of serious adverse events and of the conclusions of their research.

(2) The tissue bank shall be obliged to take the following in respect of all serious adverse events or suspicions referred to in Article 8 of this Ordinance and serious adverse events or suspicions observed in the tissue bank:

- inform the Ministry without delay and submit all available information,

- perform a cause-and-effect relationship analysis,

- without delay, upon completion of the research, submit a conclusion to the Ministry,

- investigate serious adverse events and take corrective action to prevent recurrence of the cause.

(3) The conclusion referred to in paragraph 1 of this Article must contain the data and be submitted on Form II. B which is printed in Annex II. of this Ordinance and forms an integral part thereof.

Article 11

(1) The tissue bank is obliged to keep records of serious adverse events, research conclusions and measures taken.

(2) The tissue bank is obliged to submit to the Ministry an annual report on serious adverse events no later than 1 March of the current year for the previous year.

(3) The report referred to in paragraph 2 of this Article must contain data and be submitted on Form III. B which is printed in Annex III. of this Ordinance and forms an integral part thereof. The annual report on serious adverse events must also be submitted in electronic form.

Article 12

The responsible person of the tissue bank is in charge of collecting data from the forms of this Ordinance and submitting the form to the Ministry.

REPORTING SERIOUS ADVERSE REACTIONS AND EVENTS REQUIRING URGENT TREATMENT

Article 13

(1) Health care institutions that perform activities of collecting, taking or applying tissue and tissue banks are obliged to establish an effective system of urgent reporting of serious adverse reactions and events that require urgent action due to the danger of imminent threat to public health.

(2) The responsible person of the tissue bank is obliged to notify the Ministry of the National Transplant Network (abbreviated: NTM) without delay upon receipt of the report on serious adverse reactions, serious adverse events, suspicion of a serious adverse reaction or event referred to in paragraph 1 of this Article.

(3) Upon receipt of the notification referred to in paragraph 2 of this Article, the Ministry shall assess the adverse reaction or event and determine proposals for action.

Article 14

(1) The tissue bank must ensure the existence and implementation of a fast, accurate and confidential procedure for the withdrawal of distributed tissue referred to in Article 13 of this Ordinance.

(2) The tissue bank shall be obliged to inform the Ministry on the course of the procedures referred to in paragraph 1 of this Article.

TRACEABILITY

Article 15

The tissue bank must have an effective and accurate system of unique identification and labeling of tissues that have been received and distributed.

Article 16

(1) The tissue bank and the health institution that performs the activity of tissue application are obliged to keep data on the donor / recipient for at least 30 years. The minimum information is printed in Annex IV to this Ordinance and forms an integral part thereof.

(2) The institutions referred to in paragraph 1 of this Article are obliged to preserve the minimum data on the donor / recipient in a legible condition.

Article 17

(1) In addition to the procedure referred to in Article 13, paragraph 3 of this Ordinance, the Ministry shall perform the following tasks:

1. establishing and maintaining a database (register) of serious adverse events and serious adverse reactions,

2. assessing reports of serious adverse reactions and events received from tissue banks, tissue collection and transplantation institutions, other Member States of the European Union, third countries and other participants, and identifying the necessary measures,

3. participating in the international system for reporting serious adverse reactions and events to tissues,

4. informing tissue banks of serious adverse reactions and events on the basis of information received from other sources,

5. monitoring the efficiency of the system referred to in Article 13, paragraph 1 of this Ordinance,

6. preparing and submitting an annual report on reported serious adverse events and serious adverse reactions to the European Commission no later than 30 June of the current year for the previous year on Form III. A and III. B which are printed in Annex III. of this Ordinance and form an integral part thereof.

Article 18

With the entry into force of this Ordinance, the Ordinance on the manner of reporting, the manner of keeping records and deadlines for reporting on serious adverse events and serious adverse reactions shall cease to be valid (Official Gazette 67/09).

Article 19

This Ordinance shall enter into force on the eighth day following that of its publication in the Official Gazette.

Class: 011-02 / 13-02 / 40

Reg. No.: 534-10-1-1-1 / 3-13-1

Zagreb, 17 April 2013

Minister

prof. dr. sc. Rajko Ostojić, Ph.D. med., vr

ANNEX I

REPORT OF SERIOUS ADVERSE REACTIONS (OŠR)

I.A Form of suspicion of a serious adverse reaction

Health institution:
Tissue bank:
Application number
Application date (year / month / day)
OŠR is observed in: donor recipient
Date of collection in humans (year / month / day)
Date of application in humans (year / month / day)
Collection point in humans (year / month / day)
Place of application in humans (year / month / day)
Unique donor identification number
Date of serious adverse reaction (year / month / day)
The type of tissue and cells for which a serious adverse reaction is suspected
Type of potentially serious adverse reactions
Name and surname of the person applying Signature
Date

I.B Form of conclusion of the investigation of serious adverse reactions

Health institution:
Tissue bank:
Application number
Application date (year / month / day)
Confirmation of a serious adverse reaction (yes / no)
Date of confirmation of a serious adverse reaction (year / month / day)
Unique donor identification number
Change of ORS type compared to the type initially reported (yes / no) If yes, please specify
Clinical outcome (if known)

- complete recovery - minor consequences - serious consequences - death
Outcome of the investigation and final conclusions
Description of measures taken and recommendations for the implementation of preventive measures
Name and surname of the person applying Signature
Date

ANNEX II

REPORT OF SERIOUS HARMFUL EVENTS (OŠD)

II.A Serious adverse event report form

Health institution:				
Tissue bank:				
Application number				
Application date (year / month / day)				
Date of serious adverse event (year / month / day)				
Serious adverse event that may affect the quality and safety of tissues and cells due to non-compliance in:	Specifications			
	Tissue or cell mismatch	Equipment	Human error	Other
Collecting				
Testing				
Process				
Preservation				
Save				
Distribute				
Transportation				
Materials				
Other (specify)				

Name and surname of the person applying Signature
Date

II.B Form of conclusion of the investigation into serious adverse events

Tissue bank
Application number
Application date (year / month / day)
Confirmation of a serious adverse event (yes / no)
Date of confirmation of a serious adverse event (year / month / day)
Analysis of causal relationship (details)
Corrective action taken (details)
Name and surname of the responsible person Signature
Date

ANNEX III

ANNUAL APPLICATIONS

III.A Report form of serious adverse reactions for the year_____

Tissue bank			
Period: January 1 - December 31 (year)			
Number of serious adverse reactions according to tissue and cell type or media and materials in contact with tissues and cells			
	Tissue / cell type (or media and materials in contact with tissues and cells)	Number of serious adverse reactions	Total number of distributed tissues / cells of this species (if available)
1.			
2.			
3.			
...			
Total			
Number of all distributed tissues / cells (including tissue type and cells for which no serious adverse reaction was recorded)			

Number of ORS observed in recipients (total number of recipients):		
Type of serious adverse reactions reported		Total number of serious adverse reactions
Transmitted bacterial infections		
Transmitted viral infections	HBV	
	HCV	
	HIV-1/2	
	Another (specify)	
Transmitted parasitic infections	Malaria	
	Another (specify)	
Transmitted malignant diseases		
Other transmitted diseases		
Other serious reactions (specify)		
Name and surname of the responsible person Signature		

III.B Report form of serious adverse events for the year_____

Tissue bank				
Period: January 1 - December 31 (year)				
Total number of tissues and cells treated				
The total number of serious adverse events that could affect the quality and safety of tissues and cells due to non-compliance in:	Specifications			
	Tissue or cell mismatch	Equipment	Human error	Other
Taking				
Testing				
Processing				
Preservation				
Storage				
Distribute				
Transportation				
Materials				

Other (specify)				

Name and surname of the responsible person Signature

ANNEX IV

Minimum data on the donor / recipient kept:

A. TISSUE BANKS

Donor identification

Donation identification:

- identification of the institution collecting tissues or tissue banks

- unique number of donations

- unique donor number

- date of collection

- place of collection

- type of donation (eg one - more tissues; autologous - allogeneic; living - deceased donor)

Transplant identification:

- tissue bank identification

- tissue and cell / graft type (basic nomenclature)

- pool number (if applicable)

- number of grafts divided into several recipients (split) (if applicable)

- expiry date

- tissue / cell status (i.e. quarantined, suitable for use, etc.)

- description and origin of the graft, applied processing procedures, materials and media in contact with tissues and cells that affect their quality and / or safety

- identification of the institution that performed the final marking

Identification of use in humans:

- the date of distribution of the graft or the decision on destruction

- identification of the doctor who performed the transplant and the institution where the transplant was used

B. INSTITUTIONS USING TISSUES AND HUMAN CELLS

(a) Identification of the tissue bank that distributed the tissues and cells

(b) Identification of the doctor who performed the transplant and the institution where the transplant was performed

(c) Tissue and cell type

(d) Transplant identification

(e) Identification of the recipient

(f) Date of application

MINISTRY OF HEALTH

1112

Pursuant to Article 29, paragraph 6 and Article 30, paragraph 2 of the Human Organ Transplantation for Medical Purposes Act (Official Gazette 144/2012), the Minister of Health shall issue

RULES ON CONDITIONS REGARDING PREMISES, WORKERS, MEDICAL-TECHNICAL EQUIPMENT, QUALITY AND SAFETY FOR PERFORMING THE ACTIVITY OF ORGAN COLLECTION AND TRANSPLANTATION

Article 1

This Ordinance prescribes the conditions regarding space, workers and medical-technical equipment, quality and safety that must be met by health care institutions in order to perform the activity of taking and transplanting organs.

Article 2

This Ordinance transposes into the legal order of the Republic of Croatia Directive 2010/53 / EC of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 243, 16.9.2010).

Article 3

Health care institutions that can perform the activity of taking and transplanting organs (hereinafter: transplant center) must meet the sanitary, hygienic and other requirements prescribed by the Ordinance on minimum requirements for space, workers and medical equipment for health care and special conditions prescribed by this Ordinance.

Article 4

(1) The transplantation center for each transplantation program must have at least:

- head of the transplant program,

- a multidisciplinary team of health workers of the appropriate specialty for organ transplantation (hereinafter: the transplant team),

- a team of health workers of the appropriate specialty for organ harvesting (hereinafter: explant team),

- clinical coordinator.

(2) The head of the transplantation program referred to in paragraph 1, subparagraph 1 of this Article shall be appointed by the director of the transplantation center at the proposal of the expert council of the health institution for a period of 4 years.

(3) The head of the transplantation program is responsible for the professional training and education of the members of the transplantation team, the quality system of the transplantation

program and participates in national and international professional bodies and meetings within its scope.

(4) In addition to the health care workers referred to in paragraph 1 of this Article, the transplantation center must have at its disposal a psychiatrist or a person with a master of psychology with appropriate experience in evaluating potential living donors, family interactions and psychological support to the transplant team, organ recipients and patients, or with a master of social policy to implement a social rehabilitation program for organ recipients.

(5) The transplant center must also have a transplant administrator who is responsible for the administrative management of medical records and ensuring traceability within the scope of the transplant clinic and the competence of the transplant program.

(6) For the activity of organ transplantation in patients - children, members of the transplant team must have proven experience in transplantation of individual organs in patients - children, and the transplant team must have a doctor of medicine, pediatrician of the appropriate specialty.

Kidney transplant program

Article 5

A transplant center with a kidney transplant program in terms of space must have:

- at least 2 operating theaters,

- Department of Internal Medicine,

- Department of surgical activities,

- Department of Radiology,

- Department of Anesthesiology, Resuscitation and Intensive Care,

- availability of the pathology department with experience in the interpretation of histological kidney biopsies,

- Department of Nephrology with dialysis facilities,

- Department of Urology with experience in performing histological biopsies of the kidneys,

- at least one isolation unit for direct monitoring of the condition of patients after organ transplantation,

- transplant clinic,

- constant availability of microbiological diagnostics,

- constant availability of blood products,

- constant availability of conservative and interventional radiological diagnostics,

- constant availability of a toxicological laboratory for monitoring the concentration of immunomodulatory drugs,

- availability of tissue typing laboratories accredited by the European Society of Immunogenetics (EFI).

Article 6

The head of the transplant program is a member of the transplant team with the greatest experience and competencies in the field of kidney transplantation treatment and scientific and professional contribution in its field.

Article 7

The kidney transplant team consists of a transplant surgeon, a transplant nephrologist, and a transplant anesthesiologist.

Article 8

(1) The transplant surgeon referred to in Article 7 of this Ordinance is a doctor of medicine specializing in urology or a specialist in general surgery or a specialist in general surgery with a narrower specialization in digestive (abdominal) surgery or a specialist in abdominal surgery.

(2) The transplant surgeon referred to in paragraph 1 of this Article must have two years of education in a transplant center with a kidney transplant program during which he is obliged to:

- participate in at least 20 kidney transplants, of which at least 10 as a first surgeon and at least 10 as an assistant. All transplants must be documented and certified by the transplant center where they were performed,

- perform at least 20 kidney explants, of which at least 10 as a first surgeon and at least 10 as an assistant.

(3) Exceptionally, if the transplant surgeon does not meet the conditions referred to in paragraph 2 of this Article, he may be recognized for his clinical experience with the confirmation of the transplant center, if he has performed:

- 30 or more kidney transplants as the first surgeon in the last 5 years,

- at least 15 kidney explants.

(4) For transplantation of kidneys from living donors, the transplant surgeon, in compliance with the conditions referred to in paragraph 2 or 3 of this Article, must have a certificate from the transplant center that he has performed at least 30 open kidney procedures during 2 years.

(5) If laparoscopic nephrectomies are performed in the transplant center, the transplant surgeon must have experience in at least 15 laparoscopic nephrectomies over 5 years. All laparoscopic nephrectomies must be documented and certified by the health care facility where they were performed.

(6) In the transplantation center where kidney transplantation is performed in children, the transplant surgeon must have experience in kidney transplantation in children.

Article 9

(1) The transplant nephrologist referred to in Article 7 of this Ordinance is a doctor of medicine specializing in nephrology or a specialist in internal medicine with a specialization in nephrology with two years of education in a transplant center with a kidney transplant program during which:

- Acquired competencies in the field of transplantation medicine including care for patients in the final stages of kidney disease, selection of recipients, basics of immunogenetics, postoperative and later care of patients, use of immunosuppressive therapy, differential diagnosis and interpretation of renal dysfunction test results, and long-term patient monitoring and care,

- cooperated with the transplant surgeon on preoperative assessment and postoperative care as well as the treatment of hypertension, diabetes and hemodialysis problems,

- participated in the care of at least 30 hospitalized transplant patients,

- participated in the follow-up of at least 30 patients of transplant discharged from the hospital over a period of one year,

- attended at least 3 kidney transplants in the operating room.

(2) If the transplant nephrologist does not meet the conditions referred to in paragraph 1 of this Article, he may be recognized for his clinical experience, provided he:

- has a documented involvement in the care of 45 or more kidney transplant patients over the past 5 years,

- was present in the operating room during at least 3 transplants and 3 kidney explants,

- has participated in at least 3 assessments and preparations of potential donors, including the preparation of at least 3 multi-organ donors where one of the organs taken is a kidney,

- has participated in the care of patients of transplant for the past five years and has the knowledge and skills of care in the final stages of kidney disease, recipient selection, basics of histocompatibility and tissue typing, postoperative and subsequent patient care, basics of immunosuppressive therapy and side effects and complications of immunosuppression differential diagnostics and interpretation of renal dysfunction test findings in allogeneic recipients, interpretation of histological biopsy findings, and long-term patient monitoring and care.

Article 10

(1) The transplant anesthesiologist referred to in Article 7 of this Ordinance is a doctor of medicine specializing in anesthesiology, resuscitation and intensive care or a specialist in anesthesiology, resuscitation and intensive care with specialization in intensive care with two years of work experience in a transplant center with a kidney transplant program and has:

- directly participated in the preoperative preparation and anesthesia of 45 kidney transplant patients,

- participated in intensive care and resolution of complications during transplantation and post-intensive care of at least 45 patients with organ transplantation,

- mastered the knowledge and skills of preoperative preparation, anesthesia and intensive care of organ transplant patients, including therapeutic approaches and use of immunosuppressive therapy, side effects and complications, basics of histocompatibility and tissue typing, differential diagnosis and interpretation of histological biopsy findings.

(2) In the transplantation center where kidney transplantation is performed in children, the transplant anesthesiologist must have experience in anesthesia of children.

Article 11

(1) The clinical coordinator is a doctor of medicine specializing in nephrology or urology or a bachelor of nursing with at least 5 years of work experience and at least 3 years of experience in the care and nursing of patients who have had a kidney transplant.

(2) The clinical coordinator is responsible for:

- coordination of clinical care of the patient before and after organ transplantation,

- daily communication with dialysis centers and coordination of clinical treatment of the patient,

- administrative management of the waiting list,

- entry of data in the prescribed registers, and

- education of the patient and his family.

(3) The clinical coordinator cooperates with the transplant team and services involved in patient care, and may be involved in procedures related to organ harvesting, which include receiving kidney offer, organizing and supporting the explant team and admitting the patient to the hospital.

Article 12

(1) The explantation team for the kidney consists of a doctor of medicine, urology specialist or general surgery specialist or general surgery specialist with a narrower specialization in digestive (abdominal) surgery or abdominal surgery specialist and a bachelor of nursing.

(2) The medical doctor referred to in paragraph 1 of this Article must have a certificate of at least 10 kidney explants performed independently.

(3) The medical doctor referred to in paragraph 1 of this Article is responsible for organizing the explant procedure, checking the identity and characteristics of the donor, reporting adverse reactions and events, submitting the prescribed documentation, proper labeling and packaging of organs and communication with the clinical coordinator.

Pancreas transplant program

Article 13

(1) A transplantation center with a transplantation program for the pancreas in terms of space must meet the requirements referred to in Article 5 of this Ordinance and have a gastroenterology department.

(2) The transplantation center referred to in paragraph 1 of this Article may perform a pancreas transplantation program if it has at least 10 kidney transplant procedures per year.

Article 14

The head of the transplant program is a member of the transplant team with the greatest experience and competencies in the field of treatment by the method of pancreas transplantation and scientific and professional contribution in its field.

Article 15

The pancreas transplant team consists of a pancreas transplant surgeon, a transplant internist, and a transplant anesthesiologist.

Article 16

(1) The pancreas transplant surgeon referred to in Article 15 of this Ordinance is a doctor of medicine specializing in general surgery or abdominal surgery or vascular surgery or general surgery with a narrow specialization in digestive (abdominal) surgery or a specialist in general surgery with a narrow specialization in vas specialization.

(2) The pancreas transplant surgeon referred to in paragraph 1 of this Article must have:

- performed at least 5 pancreas transplants during the past two years as the first surgeon. All transplants must be documented and certified by the health institution where they were performed,

- performed at least 5 pancreatic explants as the first surgeon in two years.

(3) Exceptionally, if the pancreas transplant surgeon does not meet the conditions referred to in paragraph 2 of this Article, he may be recognized for his clinical experience, if he meets the following conditions:

- has assisted 20 or more pancreas transplants in the past 5 years, of which at least 10 as a first surgeon and at least 10 as an assistant. All transplants must be documented and certified by the health institution where they were performed,

- at least 10 pancreatic explants have been performed. All explants must be documented and certified by the transplant surgeon who supervised the procedures. Certificates must contain the date of transplantation, medical history, description of work during the procedure.

Article 17

(1) The transplant internist referred to in Article 15 of this Ordinance is a doctor of medicine specializing in nephrology or a specialist in internal medicine with a specialization in nephrology or a specialist in endocrinology and diabetology or a specialist in internal medicine with a specialization in endocrinology and diabetology.

(2) The transplant internist referred to in paragraph 1 of this Article must have one year of education in a transplant center with a pancreas transplant program that performs at least 10 pancreas transplants per year.

(3) During the work in the transplantation center referred to in paragraph 2 of this Article, the transplant internist is obliged to:

- under direct supervision, participate in the preparation and postoperative care and monitoring of at least 10 patients of transplant. All cases must be documented and certified by the transplant physician who supervised the procedures. Certificates must contain the date of the transplant, medical history and a description of the work,

- master knowledge and skills in the field of transplantation medicine, including care for patients with diabetes mellitus and patients with other pancreatic diseases, selection of donors and recipients, pre- and postoperative hemodynamic care, use of mechanical aids, postoperative immunosuppressive therapy and interpretation of the biological degree of rejection and long-term monitoring and care of the patient,

- be present in the operating room for at least 3 pancreas transplants and at least 3 organ explants and attend and observe at least one donor assessment procedure and the entire organ donation process and participate in at least 3 multi-organ explants in which the pancreas is explanted.

(4) Exceptionally, if the transplant internist does not meet the conditions referred to in paragraphs 2 and 3 of this Article, he may be recognized for clinical experience if he meets the following conditions:

- has a documented involvement in the care of 10 or more pancreatic transplant patients for 2 years. Participation in patient care and monitoring must be at least 3 months continuous from the transplantation for each patient and documented and certified by the health institution where they were performed,

- must have been present in the operating room for at least 3 pancreas transplants and 3 explanations of any organ. In addition, he must have participated in at least 3 assessments of potential donors and the preparation of the donor, including the preparation of at least 3 multi-organ donors where one of the donated organs is the pancreas,

- must have participated in the care of patients of transplant during the past two years and mastered the knowledge and skills of care for patients with diabetes and pancreatic diseases, selection of donors and recipients, pre- and postoperative hemodynamic care, postoperative immunosuppressive therapy, interpretation of histological findings and biopsy assessment. and long-term patient monitoring and care.

Article 18

The transplant anesthesiologist referred to in Article 15 of this Ordinance is a doctor of medicine specializing in anesthesiology, resuscitation and intensive care or a specialist in anesthesiology, resuscitation and intensive care with a specialization in intensive care, who must have two years of experience in a transplant center with a pancreas transplant program. He has:

- directly participated in the preoperative preparation and anesthesia of 10 patients for pancreas transplantation,

- participated in intensive care and resolution of possible complications during transplantation and post-intensive care of at least 10 patients of transplant,

- mastered the knowledge and skills of all aspects of preoperative preparation, anesthesia and intensive care of patients of transplant, including therapeutic approaches and the use of immunosuppressive therapy, side effects and complications, differential diagnosis and interpretation of histological biopsy findings.

Article 19

(1) The clinical coordinator is a doctor of medicine specializing in the appropriate specialty or a bachelor of nursing with at least 5 years of work experience and at least 3 years of experience in the care and nursing of patients who have had a pancreas transplant.

(2) The clinical coordinator is responsible for the coordination of clinical care for the patient before and after the pancreas transplantation and participates in the education of the patient and his family.

(3) The clinical coordinator cooperates with the transplant team and services involved in patient care, and may be involved in procedures related to organ harvesting, which include receiving organ offers, organizing and supporting the explant team and admitting patients to the hospital.

Article 20

(1) The pancreas explantation team consists of a doctor of medicine specializing in general surgery or a specialist in general surgery with a narrower specialization in digestive (abdominal) surgery or a specialist in abdominal surgery and a nurse / medical technician.

(2) The medical doctor referred to in paragraph 1 of this Article must have a certificate for having independently performed at least 10 pancreatic explants.

(3) The medical doctor referred to in paragraph 1 of this Article is responsible for organizing the explant procedure, verifying the identity and assessment of donor characteristics, reporting adverse reactions and events, submitting prescribed documentation, proper labeling and packaging of organs and communication with the clinical coordinator.

Liver transplant program

Article 21

The transplant center with a liver transplant program must have in terms of space:

- 3 operating theaters

- Department of Gastroenterology,

- Department of Internal Medicine,

- Department of General Surgery

- Department of Radiology,

- Department of Anesthesiology, Resuscitation and Intensive Care,

- availability of a pathology department with experience in the interpretation of histological liver biopsies,

- one isolation unit for direct monitoring of patients' condition after organ transplantation,

- transplant clinic,

- constant availability of microbiological diagnostics,

- constant availability of blood products,

- constant availability of conservative and interventional radiological diagnostics,

- constant availability of a toxicological laboratory for monitoring the concentration of immunomodulatory drugs.

Article 22

The head of the transplant program is a member of the transplant team with the greatest experience and competencies in the field of liver transplantation treatment and scientific and professional contribution in its field.

Article 23

The liver transplant team consists of a transplant surgeon, a transplant internist, and a transplant anesthesiologist.

Article 24

(1) The transplant surgeon referred to in Article 23 of this Ordinance is a general practitioner or abdominal surgery specialist or vascular surgery specialist or general surgery specialist with a narrow specialization in digestive (abdominal) surgery or a general surgery specialist with a narrow specialization in vascular surgery.

(2) The transplant surgeon referred to in paragraph 1 of this Article must have two years of education in a transplant center with a liver transplant program that performs at least 30 liver transplants per year.

(3) During the two-year education referred to in paragraph 2 of this Article, the transplant surgeon is obliged to:

- perform at least 20 liver transplants, of which 10 as a first surgeon and 10 as a first assistant. All transplants must be documented and certified by the health institution where they were performed,

- perform at least 20 liver explants, of which 10 as a first surgeon and 10 as an assistant,

- be directly involved in the care of liver transplant patients,

- master the knowledge and skills of patient care in the final stages of liver disease, selection of recipients, basics of histocompatibility and tissue typing, postoperative and later patient care, use of immunosuppressive therapy, differential diagnosis and interpretation of liver function test results, interpretation of histological findings and long biopsy findings and patient care.

(4) Exceptionally, if the transplant surgeon does not meet the conditions referred to in paragraphs 2 and 3 of this Article, he may be recognized for his clinical experience, if he meets the following conditions:

- has participated in 20 or more liver transplants, of which 10 as a first surgeon and 10 as an assistant during the last 5 years. All transplants must be documented and certified by the health center where they were performed. Certificates must contain the date of the transplant, medical history, a description of the candidate's work during the procedure. During each of these years of experience he must have preoperative care activities and operations as the first surgeon,

- has performed at least 20 liver explants, of which 10 as a first surgeon and 10 as an assistant,

- must be directly involved in pre-transplant preparation and care of liver transplant patients for 5 years.

Article 25

In order to perform the activity of liver transplantation from living donors, the transplant surgeon must, in addition to meeting the conditions referred to in Article 24 of this Ordinance, also meet the following conditions:

- that during the past 2 years he participated as the first surgeon in at least 20 operations - liver resection with more than 3 segments,

- that he has participated in at least 5 liver donation procedures from a living donor.

Article 26

(1) The transplant internist referred to in Article 23 of this Ordinance is a doctor of medicine specializing in gastroenterology or a specialist in internal medicine with a narrower specialization in gastroenterology.

(2) The transplant internist must have one year of education in a transplant center with a liver transplant program during which he is obliged to:

- participate, under direct supervision, of at least 3 months in the care of patients of transplant, and spend the rest of the time in jobs related to transplantation, such as work in the tissue typing laboratory,

- master knowledge and skills in the field of transplantation medicine including care for patients in the final stages of liver disease, selection of recipients, basics of histocompatibility and tissue typing, postoperative and later care of patients, use of immunosuppressive therapy, differential diagnosis and interpretation of liver dysfunction tests. biopsy findings and long-term monitoring and patient care,

- cooperate with surgeons on preoperative assessment and postoperative care as well as treatment,

- participate in the work of the transplant team and be involved in decision-making on immunosuppressive therapy,

- to participate in the care of at least 30 hospitalized transplant patients for 12 months as well as in the monitoring / control of at least 30 patients discharged from the hospital. Monitoring of discharged patients must be continuous for at least 3 months after discharge from the hospital,

- be present in the operating room for at least 3 liver transplants and at least 3 explants,

- attend and observe at least one donor assessment procedure and the entire organ donation procedure, and

- participate in at least 3 multiorgan explants.

(3) Exceptionally, if the transplant internist does not meet the conditions referred to in paragraph 2 of this Article, he may be recognized for clinical experience, if he meets the following conditions:

- has a documented involvement in the care of at least 25 or more liver transplant patients in the last 5 years. Participation in the care and monitoring of patients must be continuous for at least three months from discharge from the hospital for each patient and documented and certified by the transplant center in which they were performed,

- must be present in the operating room for at least 3 transplants and 3 liver explants. In addition, it must observe / participate in at least 3 assessments of potential donors and donor preparation including the preparation of at least 3 multi-organ donors where one of the donated organs is the liver,

- must participate in the care of patients of transplant during the past two years and master the knowledge and skills of care in the final stages of liver disease, selection of recipients, basics of histocompatibility and tissue typing, postoperative and subsequent patient care, use of immunosuppressive therapy and side effects and complications of immunosuppression and interpretations of liver dysfunction test findings, interpretation of histological biopsy findings, and long-term follow-up and patient care.

Article 27

The transplant anesthesiologist referred to in Article 23 of this Ordinance is a doctor of medicine specializing in anesthesiology, resuscitation and intensive care or a specialist in anesthesiology, resuscitation and intensive care with a specialization in intensive care who must have two years of experience in a transplant center with a liver transplant program. who:

- directly participated in the preoperative preparation and anesthesia of 30 liver transplant patients,

- participated in intensive care and resolution of possible complications during transplantation and post-intensive care for at least 30 patients of transplant.

Article 28

(1) The clinical coordinator is a doctor of medicine specializing in the appropriate specialty or a bachelor of nursing with at least 5 years of work experience and at least 3 years of experience in the care and nursing of patients who have had a liver transplant.

(2) The clinical coordinator is responsible for the coordination of clinical care for the patient before and after liver transplantation and participates in the education of the patient and his family.

(4) The clinical coordinator cooperates with the transplant team and services involved in patient care, and may be involved in procedures related to organ harvesting, which include receiving organ offers, organizing and supporting the explant team and admitting the patient to the hospital.

Article 29

(1) The explantation team for the liver consists of a doctor of medicine, a surgeon specializing in general or abdominal surgery and a bachelor of nursing.

(2) The medical doctor referred to in paragraph 1 of this Article must have a certificate of at least 10 liver explants performed independently.

(3) The medical doctor referred to in paragraph 1 of this Article is responsible for organizing the explantation procedure, verifying the identity and assessment of donor characteristics, reporting adverse reactions and events, filling in and submitting prescribed documentation, proper labeling and packaging of organs and communication with the clinical coordinator.

Liver transplant program in children

Article 30

In order to perform liver transplantation activities in children, the transplantation center with a liver transplantation program in children in terms of space must have:

- 3 operating theaters, of which at least one is specifically equipped for the needs of the pediatric population,

- Department of Pediatric Gastroenterology,

- Department of Pediatric and Abdominal (Transplant) Surgery,

- intensive care unit for children,

- Department of Pathology with experience in the interpretation of histological findings of the liver specific to the pediatric population and transplantation issues in general,

- isolation within the intensive care unit for children,

- semi-isolation within the Department of Pediatric Gastroenterology,

- transplant clinic,

- constant availability of microbiological diagnostics,

- constant availability of blood products,

- constant availability of conservative and interventional radiological diagnostics,

-constant availability of a toxicological laboratory for monitoring the concentration of immunomodulatory drugs.

Article 31

The head of the transplant program is a member of the transplant team with the greatest experience and competencies in the field of liver transplantation in children and scientific and professional contribution in its field.

Article 32

The pediatric liver transplant team consists of a pediatric liver transplant surgeon, a transplant pediatric gastroenterologist, a pediatric transplant anesthesiologist and a pediatric intensivist.

Article 33

(1) The pediatric liver transplant surgeon referred to in Article 32 of this Ordinance is a doctor of medicine specializing in pediatric surgery or a specialist in general surgery.

(2) The pediatric liver transplant surgeon referred to in paragraph 1 of this Article must have two years of education in a transplant center with a liver transplant program which must have at least 30 adult liver transplants and 5 children's liver transplants per year.

(3) During the two-year education referred to in paragraph 2 of this Article, the liver transplant surgeon is obliged to:

- participate in at least 20 liver transplants, of which 10 as a first surgeon and 10 as a first assistant,

- perform at least 2 liver transplants in children as the first surgeon and 2 as the first assistant. All transplants must be documented and certified by the health institution where they were performed,

- perform at least 20 liver explants, of which 10 as a first surgeon and 10 as an assistant,

- be directly involved in the care of patients with liver transplantation and must master the knowledge and skills of care for patients in the final stages of liver disease, selection of recipients, postoperative and subsequent patient care, use of immunosuppressive therapy, differential diagnosis and interpretation of liver function tests, interpretation histological findings of biopsy and long-term follow-up and patient care.

(4) Exceptionally, instead of a pediatric liver transplant surgeon, a liver transplant surgeon referred to in Article 24 of this Ordinance may participate in the transplant team, provided that in the last 5 years:

- participated in at least 20 procedures as the first surgeon which included generous resections and hepatobiliary tract surgery in pediatric patients,

- has performed at least 10 liver explants, of which 5 as a first surgeon and 5 as an assistant,

- was directly involved in pre-transplant preparation and care of liver transplant patients for 5 years.

(5) If a pediatric liver transplant surgeon assesses that the optimal performance of vascular anastomoses in infants requires the participation of a doctor of medicine specializing in general surgery, a specialty in plastic surgery or a doctor of medicine specializing in plastic, reconstructive and aesthetic surgery and a doctor of medicine, specialist in general surgeon specialty vascular surgery or doctor of medicine specialist vascular surgery, the same can join the transplant team if he has documented experience in pediatric transplantation of at least 15 procedures in 5 years.

Article 34

(1) The transplant pediatric gastroenterologist referred to in Article 32 of this Ordinance is a doctor of medicine who is a pediatric specialist with a narrower specialization in gastroenterology.

(2) The transplant pediatric gastroenterologist referred to in paragraph 1 of this Article must have one year of experience in a transplant center with a liver transplant program during which he is obliged to:

- participate under direct supervision of at least 6 months in the care of patients of transplant, and spend the rest of the time on transplant-related tasks,

- master a wide range of knowledge in the field of transplantation medicine including care for patients in the final stages of liver disease, selection of recipients, basics of histocompatibility and tissue typing, postoperative and later patient care, use of immunosuppressive therapy, differential diagnosis and interpretation of liver dysfunction tests, interpretation of liver dysfunction tests, biopsy findings and long-term monitoring and patient care,

- co-decide with surgeons in preoperative assessment and postoperative care as well as treatment,

- participate in the work of the transplant team and be involved in decision-making on immunosuppressive therapy,

- participate in the care of at least 10 hospitalized transplant patients as well as in the monitoring / control of at least 10 patients discharged from the hospital. Monitoring of discharged patients must be continuous after discharge from the hospital,

- be present in the operating room for at least 3 liver transplants and at least 3 explants, and

- observe and attend at least one donor assessment procedure and the entire organ donation procedure.

(3) Exceptionally, if the transplant pediatric gastroenterologist for the liver does not meet the conditions referred to in paragraph 2 of this Article, he may be recognized for clinical experience if he meets the following conditions:

- has a documented involvement in the care of 15 or more liver transplant patients in the last 5 years. Participation in the care and monitoring of patients must be continuous from discharge from the hospital for each patient and documented and certified by the transplant center in which they were performed,

- must be present in the operating room for at least 3 transplants and 3 liver explants,

- must observe / participate in at least 3 assessments of potential donors and donor preparation including the preparation of at least 1 multi-organ donor where one of the donated organs is the liver,

- must participate in the care of patients of transplant for two years and possess knowledge and skills of care in the final stages of liver disease, selection of recipients, postoperative and subsequent patient care, use of immunosuppressive therapy and side effects and complications of immunosuppression, differential diagnosis and interpretation of dysfunction, interpretation of histological biopsy findings and long-term follow-up and patient care.

Article 35

(1) A pediatric transplant anesthesiologist referred to in Article 32 of this Ordinance is a doctor of medicine specializing in anesthesiology, resuscitation and intensive care or a specialist in anesthesiology, resuscitation and intensive care with at least two years of experience in anesthesia of children.

(2) A pediatric transplant anesthesiologist must have two years of work experience in a transplant center with a liver transplant program during which he directly participated in preoperative preparation and anesthesia of 30 patients (of which at least 10 children) for liver transplantation and resolving possible complications during transplantation and participated in post-transplant care of at least 10 children.

Article 36

A pediatric intensive care physician is a pediatrician with a specialization in intensive care who must have at least 3 years of work experience as a pediatric intensive care physician in a transplant center with a pediatric liver transplant program and in that period directly and actively participate in the care of at least 10 children with liver transplant.

Article 37

(1) The clinical pediatric coordinator is a doctor of medicine specializing in the appropriate specialty or a bachelor of nursing with at least 5 years of work experience and at least 3 years of experience in the care and nursing of patients who have had a liver transplant.

(2) The clinical pediatric coordinator is responsible for the coordination of clinical care for the patient before and after organ transplantation and participates in the education of the patient and his family.

(3) The clinical pediatric coordinator cooperates with the transplant team and services involved in patient care, and may be involved in procedures related to organ harvesting, which include receiving organ offers, organizing and supporting the explant team and admitting the patient to the hospital.

Article 38

In order to perform liver transplantation from living donors and exceptionally when there is no pediatric transplant surgeon, the liver transplant surgeon referred to in Article 24 of this Ordinance must also meet the following conditions:

- that during the past 2 years he participated as the first surgeon in at least 20 operations - liver resection with more than 3 segments,

- that he has participated in at least 5 liver donation procedures from a living donor.

Article 39

(1) The explantation team for the liver consists of a doctor of medicine, a specialist in general surgery or a specialist in abdominal surgery or a specialist in general surgery with a narrower specialization in digestive (abdominal) surgery and a bachelor of nursing.

(2) The medical doctor referred to in paragraph 1 of this Article must have a certificate of at least 10 liver explants performed independently.

(3) The medical doctor referred to in paragraph 1 of this Article is responsible for organizing the explantation procedure, verifying the identity and assessment of donor characteristics, reporting adverse reactions and events, filling in and submitting prescribed documentation, properly marking and packaging organs and communicating with the transplant coordinator.

Heart transplant program

Article 40

A transplant center with a heart transplant program in terms of space must have:

- operating room

- Department of Cardiology with proven experience in performing heart biopsies,

- a cardiac surgery department with experience of at least 300 outpatient interventions,

- Department of Pulmonology with experience in performing lung biopsies, in case of transplantation

heart / lungs,

- Department of Pathology with experience in the interpretation of heart biopsies,

- postoperative isolation,

- transplantation cardiac clinic offering inpatient and outpatient treatment and treatment of patients of transplant or patients waiting for transplantation,

- constant availability of microbiological diagnostics,

- constant availability of blood products,

- constant availability of conservative and interventional radiological diagnostics,

- constant availability of a toxicological laboratory for monitoring the concentration of immunomodulatory drugs.

Article 41

The head of the transplant program is a member of the transplant team with the greatest experience and competencies in the field of heart transplantation, and scientific and professional contribution in its field.

Article 42

The heart transplant team consists of a heart transplant surgeon, a heart transplant internist, and a transplant anesthesiologist.

Article 43

(1) The heart transplant surgeon referred to in Article 42 of this Ordinance is a doctor of medicine specializing in general surgery with a narrower specialization in cardiac surgery or a specialist in cardiothoracic surgery.

(2) The heart transplant surgeon referred to in paragraph 1 of this Article must have two years of education in a transplant center with a heart transplant program during which he is obliged to:

- perform at least 20 heart transplants as a first surgeon or first assistant. All transplants must be documented and certified by the transplant center where they were performed,

- perform at least 10 heart explants as a first surgeon or first assistant over two years.

(3) Exceptionally, if a heart transplant surgeon does not meet the conditions referred to in paragraph 2 of this Article, he may be recognized for clinical experience if he meets the following conditions:

- has performed 20 or more heart or heart / lung transplants as a first surgeon or assistant for a minimum period of 2 or a maximum of 5 years, of which a minimum of 15 must be the first surgeon. All transplants must be documented and certified by the transplant center where they were performed. Certificates must contain the date of transplantation, medical history, description of work during the procedure. During each of these years of experience, he must have preoperative care activities and operations as the first surgeon - he has performed at least 10 heart explants under professional supervision. All explants must be documented and certified by the transplant surgeon who supervised the procedures. Certificates must contain the date of transplantation, medical history, description of work during the procedure.

Article 44

(1) A heart transplant internist referred to in Article 42 of this Ordinance is a doctor of medicine specializing in cardiology or a specialist in internal medicine with a narrower specialization in cardiology.

(2) The transplant internist referred to in paragraph 1 of this Article must have one year of education in a transplant center with a heart transplant program that performs at least 20 heart or heart / lung transplants per year.

(3) During the work in the transplantation center referred to in paragraph 1 of this Article, the heart transplant internist is obliged to:

- under direct supervision, participate in the preparation and postoperative care and monitoring of at least 20 patients of transplant. All cases must be documented and certified by the transplant physician who supervised the procedure. Certificates must contain the date of the transplant, medical history and a description of the work,

- master a wide range of knowledge in the field of transplantation medicine including care for patients with acute and chronic heart failure, selection of donors and recipients, pre- and postoperative hemodynamic care, use of mechanical aids, postoperative immunosuppressive therapy, interpretation of histological findings and biopsy assessment. long-term monitoring and patient care,

- be present in the operating room for at least 3 heart transplants and at least 3 explants, and

- attend and observe at least one donor assessment procedure and the entire organ donation procedure and participate in at least 3 multiorgan explants.

(4) Exceptionally, if a heart transplant internist does not meet the conditions referred to in paragraph 3 of this Article, he may be recognized for clinical experience, if he meets the following conditions:

- has a documented involvement in the care of 20 or more heart transplant patients for a minimum period of 2 or a maximum of 5 years. Participation in patient care and monitoring must be at least 3 months continuous from the transplantation for each patient and documented and certified by the transplant center in which they were performed,

- must have been present in the operating room for at least 3 transplants and 3 heart explants. In addition, he must have observed / participated in at least 3 assessments of potential donors and donor preparation, including the preparation of at least 3 multi-organ donors where one of the donated organs is the heart or heart / lungs,

- must have participated in the care of patients of transplant during the past two years and possess knowledge and skills of care for patients with acute and chronic heart failure, selection of donors and recipients, pre- and postoperative hemodynamic care, use of mechanical aids, postoperative immunosuppressive therapy, interpretation of biological myocardium and assessment of the degree of rejection and long-term monitoring and care of the patient.

Article 45

(1) The transplant anesthesiologist referred to in Article 42 of this Ordinance is a doctor of medicine specializing in anesthesiology, resuscitation and intensive care or a specialist in anesthesiology, resuscitation and intensive care with a specialization in intensive care.

(2) The transplant anesthesiologist referred to in paragraph 1 of this Article must have two years of work experience in a transplant center with a heart transplant program during which he is obliged to:

- directly participate in the preoperative preparation and anesthesia of 10 heart transplant patients,

- participate in intensive care and resolution of possible complications during transplantation and post-intensive care of at least 10 patients of transplant,

- master the knowledge and skills of all aspects of preoperative preparation, anesthesia and intensive care of patients of transplant including therapeutic approaches and use of immunosuppressive therapy, side effects and complications, differential diagnosis and interpretation of histological biopsy findings.

Article 46

(1) The clinical coordinator is a doctor of medicine specializing in the appropriate specialty or a bachelor of nursing with at least 5 years of work experience and at least 3 years of experience in the care and nursing of patients who have had a heart transplant.

(2) The clinical coordinator is responsible for the coordination of clinical care for the patient before and after the transplant and participates in the education of the patient and his family.

(3) The clinical coordinator cooperates with the transplant team and services involved in patient care and may be involved in procedures related to organ harvesting, which include receiving organ offers, organizing and supporting the explant team and admitting patients to the hospital.

Article 47

(1) The explantation team for the heart consists of a doctor of medicine, a specialist in general surgery with a specialization in thoracic surgery or a specialist in cardiothoracic surgery and a bachelor of nursing.

(2) The doctor of medicine referred to in paragraph 1 of this Article must have a certificate of at least 10 heart explants performed independently.

(3) The medical doctor referred to in paragraph 1 of this Article is responsible for organizing the explantation procedure, verifying the identity and assessment of donor characteristics, reporting adverse reactions and events, filling in and submitting prescribed documentation, proper labeling and packaging of organs and communication with the clinical coordinator.

Lung transplant program

Article 48

A transplant center with a lung transplant program in terms of space must have:

- 2 operating theaters

- Department of Internal Medicine,

- Department of Radiology,

- Department of Anesthesiology, Resuscitation and Intensive Care,

- Department of Pulmonology,

- thoracic surgery department,

- Department of Pathology with experience in lung biopsy,

- transplant clinic,

- constant availability of microbiological diagnostics,

- constant availability of blood products,

- constant availability of conservative and interventional radiological diagnostics,

- constant availability of a toxicological laboratory for monitoring the concentration of immunomodulatory drugs.

Article 49

The head of the transplant program is a member of the transplant team with the greatest experience and competencies in the field of lung transplantation and scientific and professional contribution in its field.

Article 50

The lung transplant team consists of a lung transplant surgeon, a lung transplant internist, and a transplant anesthesiologist.

Article 51

(1) The lung transplant surgeon referred to in Article 50 of this Ordinance is a doctor of medicine specializing in general surgery with a narrower specialization in thoracic surgery or a specialist in cardiothoracic surgery.

(2) The lung transplant surgeon referred to in paragraph 1 of this Article must have one year of education in a transplant center with a lung transplant program during which he is obliged to:

- participate in at least 15 lung and / or heart / lung transplants as a first surgeon or first assistant. All transplants must be documented and certified by the transplant center where they were performed,

- perform at least 10 lung and / or heart / lung explants as a first surgeon or first assistant,

- be directly involved in the care of patients with lung transplants for two years and must master the knowledge and skills of all aspects of their care, selection of recipients, use of mechanical support, postoperative and subsequent patient care, use of immunosuppressive therapy and long-term monitoring and patient care.

(3) Exceptionally, if a lung transplant surgeon does not meet the conditions referred to in paragraph 2 of this Article, he may be recognized for clinical experience if he meets the following conditions:

- has performed 15 or more lung or heart / lung transplants as a first surgeon or assistant during a minimum period of 2 or a maximum of 5 years of which at least half of the transplants should be one or both lung wings and at least 10 transplants must be the first surgeon. All transplants must be documented and certified by the transplant center where they were performed. Certificates must contain the date of transplantation, medical history, description of work during the procedure. During each of these years of experience he must have preoperative care and surgery activities as the first surgeon,

- has participated in at least 10 lung and / or heart / lung explants under professional supervision. All explants must be documented and certified by the transplant surgeon who supervised the procedures. Certificates must contain the date of transplantation, medical history, description of work during the procedure,

- must be directly involved in the care of patients with lung transplants for two years and must master the knowledge and skills of all aspects of their care, selection of recipients, use of mechanical support, postoperative and subsequent patient care, use of immunosuppressive therapy and long-term monitoring and care. to the patient.

Article 52

(1) The lung transplant internist referred to in Article 50 of this Ordinance is a doctor of medicine, a specialist in internal medicine with a narrower specialization in pulmonology or a specialist in pulmonology.

(2) The lung transplant internist referred to in paragraph 1 of this Article must have one year of education in a transplant center with a lung transplant program.

(3) During the work in the transplantation center referred to in paragraph 2 of this Article, the lung transplant internist is obliged to:

- participate under direct supervision of the preparation and postoperative care and monitoring of at least 15 patients with transplanted lungs and / or heart / lungs. All cases must be documented and certified by the transplant physician who supervised the procedure. Certificates must contain the date of the transplant, medical history and a description of the work,

- during a minimum of two years of direct work on the transplant program, to master a wide range of knowledge in the field of transplant medicine including care for patients with acute and chronic lung failure, selection of donors and recipients, pre and postoperative hemodynamic care, use of mechanical aids, postoperative immunosuppressive therapy histological findings of lung biopsy and assessment of the degree of rejection and long-term monitoring and care of the patient,

- be present in the operating room for at least 3 lung transplants and at least 3 lung or heart / lung explants, and

- attend and observe at least one donor assessment procedure and the whole organ donation process and participate in at least 3 multiorgan explants involving both the lungs and / or the heart / lungs.

(4) If a lung transplant internist does not meet the conditions referred to in paragraphs 2 and 3 of this Article, he may be recognized for clinical experience if he meets the following conditions:

- has had a documented involvement in the care of at least 15 or more patients with lung and / or heart / lung transplantation for a minimum period of 2 or a maximum of 5 years. At least half of the patients in whose care he participated during this period should be patients with one or both lung transplants. Participation in patient care and monitoring must be at least 3 months continuous from the transplantation for each patient and documented and certified by the transplant center in which they were performed,

- has attended at least 3 lung and / or heart / lung explants in the operating room. In addition, he participated in the evaluation and preparation of a minimum of 3 possible donors, of which at least 2 are multi-organ donors of the lung or heart / lungs,

- during the past two years, he participated in the care of patients with lung transplants and mastered the knowledge and skills of care for patients with acute and chronic lung failure, selection of donors and recipients, pre and postoperative hemodynamic care, use of mechanical aids, postoperative immunosuppressive therapy lung biopsy findings and assessment of the degree of rejection and long-term monitoring and care of the patient.

Article 53

(1) The transplant anesthesiologist referred to in Article 50 of this Ordinance is a doctor of medicine specializing in anesthesiology, resuscitation and intensive care or a specialist in anesthesiology, resuscitation and intensive care with a specialization in intensive care.

(2) The transplant anesthesiologist referred to in paragraph 1 of this Article must have two years of work experience in a transplant center with a lung transplant program during which:

- directly participated in the preoperative preparation and anesthesia of 15 lung transplant patients,

- participated in intensive care and resolution of possible complications during transplantation and post-intensive care for at least 15 patients of transplant,

- mastered the knowledge and skills of all aspects of preoperative preparation, anesthesia and intensive care of patients of transplant including therapeutic approaches and use of immunosuppressive therapy, side effects and complications, basics of histocompatibility and tissue typing, differential diagnosis and interpretation of histological biopsy findings.

Article 54

(1) The clinical coordinator is a doctor of medicine specializing in the appropriate specialty or a bachelor of nursing with at least 5 years of work experience and at least 3 years of experience in the care and nursing of patients who have had a lung transplant.

(2) The clinical coordinator is responsible for the coordination of clinical care for the patient before and after the transplant and participates in the education of the patient and his family.

(3) The clinical coordinator cooperates with the transplant team and services involved in patient care and may be involved in procedures related to organ harvesting, which include receiving organ offers, organizing and supporting the explant team and admitting patients to the hospital.

Article 55

(1) The explantation team for the lungs consists of a doctor of medicine, a specialist in cardiothoracic surgery or a specialist in general surgery with a specialization in thoracic surgery and a bachelor of nursing.

(2) The medical doctor referred to in paragraph 1 of this Article must have a certificate of at least 10 lung explants performed independently.

(3) The medical doctor referred to in paragraph 1 of this Article is responsible for organizing the explantation procedure, verifying the identity and assessment of donor characteristics, reporting adverse reactions and events, filling in and submitting prescribed documentation, proper labeling and packaging of organs and communication with the clinical coordinator.

Small bowel transplant program and multiorgan transplants

Article 56

(1) The small bowel transplant program may be performed exclusively by a transplant center with a liver transplant program.

(2) Multi-organ transplantation includes transplantation of more than one organ and may be performed in a transplantation center with transplantation programs of those organs or in cooperation with several transplantation centers.

Equipment

Article 57

(1) Depending on the activity it performs, the transplantation center must, in terms of equipment, meet the conditions prescribed by the Ordinance on minimum requirements in terms of space, workers and medical-technical equipment for performing health care activities.

(2) In addition to the conditions regarding the equipment referred to in paragraph 1 of this Article, the transplantation center must also have:

- necessary surgical instruments for taking and transplanting organs,

- portable containers for storage and transfer of organs and biological samples,

- tubes for biological samples, sterile bags and organ packaging materials,

- organ preservation solutions.

(3) All packaging material must be approved for its intended purpose, including maintaining the temperature within a certain range for a certain period of time.

(4) The portable tank should be thermally insulated and made of a material that is robust enough to withstand leakage of contents, shocks, pressure changes and other possible conditions during transport.

Safety and quality

Article 58

(1) The transplantation center must provide a quality management system for organ harvesting and transplantation, including a clearly defined organizational framework, job descriptions and responsibilities for each of the jobs.

(2) The transplantation center must develop specific training programs and a plan of continuing professional development for health care workers involved in the procedures of organ harvesting and transplantation, and ensure verification of their competence to perform the assigned tasks.

(3) The transplantation center must ensure the development and application of operative procedures for:

- verification of the donor's identity,

- verification of appropriate consent,

- verification of the performed assessment of the characteristics of organs and donors,

- procurement, preservation, packaging and labeling of organs,

- organ transport,

- ensuring the traceability of organs,

- procedure for destruction of organs,

- reporting and management of serious adverse events and serious adverse reactions,

- screening and pre-transplant assessment of the recipient and management of the waiting list,

- evaluation and pre-transplantation assessment of living donors,

- transplantation procedure and immunosuppressive treatment,

- method of monitoring the health status of donors and recipients.

(4) The transplantation center must ensure preventive examinations and long-term monitoring of the health status of living organ donors and recipients, as well as the submission of data on the outcome of transplantation to the appropriate registers.

(5) The transplantation center must take all measures to ensure the safety of healthcare professionals and patients and to reduce the risk of transmission of infectious diseases to a minimum.

(6) The transplantation center must meet the requirements regarding the minimum standards of annual activity and the conditions of one-year survival outcome of patients of transplant and grafts calculated by the Kaplan Mayer method, prescribed by the Ordinance on quality and safety standards of transplant organs.

Article 59

This Ordinance shall be published in the Official Gazette and shall enter into force on the day of the accession of the Republic of Croatia to the European Union.

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Reg. No.: 534-10-1-2-2 / 4-13-2

Zagreb, 10 April 2013

Minister

prof. dr. sc. Rajko Ostojić, Ph.D. med., vr

MINISTRY OF HEALTH AND SOCIAL WELFARE

1228

Pursuant to Article 37, subparagraph 9 of the Act on the Collection and Transplantation of Parts of the Human Body for the Purpose of Treatment (Official Gazette 177/04), the Minister of Health and Social Welfare shall issue

RULEBOOK ON THE MANNER OF WORK OF THE COORDINATOR IN THE PROCEDURES OF TAKING AND TRANSPLANTING BODY PARTS FOR THE PURPOSE OF MEDICAL TREATMENT

Article 1

This Ordinance regulates the manner of work of the coordinator in the procedures of collection and transplanting body parts for the purpose of medical treatment.

Article 2

All activities related to the collection, transplantation, storage and exchange of human body parts in the Republic of Croatia are managed through the National Transplant Network.

Article 3

The National Transplant Network (hereinafter: NTM) consists of:

- National Transplant Coordinator (hereinafter: NTK),

- Transplant Coordinators (hereinafter: TK),

- Hospital Transplant Coordinators (hereinafter: BTK),

- Hospital Assistants transplant coordinators (hereinafter: PBTK).

Coordinators coordinate activities at all levels and segments of NTM activities in which constant readiness is required.

Article 4

NTKs and TKs operate within the ministry in charge of health (hereinafter: the Ministry). NTKs and TKs are appointed by the Minister in charge of health (hereinafter: the Minister). The NTK answers for its work to the Minister.

Article 5

Based on the National Transplant Program adopted by the Minister, NTK adopts the NTM work plan, is responsible for its monitoring and implementation, represents the NTM at the national and international level, is responsible for improving international cooperation and exchange of organs / tissues for transplantation, organizes and keeps records in the field of collecting, transplanting, storing and exchanging parts of the human body in the Republic of Croatia and he is responsible for

organizing and carrying out all other activities necessary for the effective accomplishment of NTM tasks.

Article 6

The TK is a member of the NTM duty team, which ensures 24-hour readiness at the Ministry for receiving and processing reports. He is responsible for advising and assisting in identifying and preparing potential donors through cooperation with the BTK, checking the status of a potential donor on the List of Non-Donors, compliance of organ and tissue allocation with prescribed and professional criteria on organ / tissue allocation to the most appropriate recipient and cooperation with related foreign and international organizations in order to exchange organs or tissues for transplantation. The TK coordinates the work of experts directly involved in the procedure. The TK takes care of the delivery of organs to the transplant center or airport with all necessary documentation. The TK is responsible for keeping the prescribed records of sampling and transplantation and, in cooperation with the BTK, for preparing the necessary documentation on a possible donor.

Article 7

The tasks of the TK on the offer of organs by a related or international transplant organization are:

- receiving the offer of organs,

- if the organ is accepted, in cooperation with a foreign coordination office, organizing transport of the organ or the departure of transplantation team for the organ,

- delivery of the samples to the laboratory that performs immunogenetic processing and tests for determining the match of recipient and donor tissues for the territory of the Republic of Croatia,

- when the organ is delivered unaccompanied by the transplant team, he takes care of it and hands it over to the responsible person in the transplant center.

Article 8

The Minister, upon recommendation by the director of the health center involved in donor selection, organ and tissue procurement and transplantation, tissue storage and typing, and tissue matching determination, shall appoint the BTK.

The BTK must be a medical doctor with the appropriate specialty with at least two years of work experience in the field of organ and tissue procurement and transplantation, who performs these duties at a full-time health care institution.

The BTK is a member of the NTM team, providing 24-hour availability for the recognition, preparation, and alerting of all possible organ/tissue donors at the hospital health care institution.

Upon proposal by the BTK, the director of the health care institution creates an organizational scheme for the recognition and preparation of possible donors and tissues that includes all services necessary for:

- identifying potential donors,

- performing death determination procedures,

- preparation and retention of potential donors,

- evaluation of acceptability of organs and tissues for transplantation,

- harmonization of organ and tissue procurement activities at the level of the health institution and the NTM.

The BTK is obliged to submit to the NTK, within 7 days from the date of adoption, the organizational scheme for identification and preparation of potential organ and tissue donors. The BTK is responsible for verifying the status of a potential donor on the List of Non-Donors, in the manner prescribed by special regulations, and for contacting the family of a potential donor in order to inform them of the upcoming procedures. The BTK is responsible for preparing and submitting all necessary data and documentation on the potential donor to ensure the quality and safety of organs and tissues. In collaboration with the TK, he/she is required to identify possible contraindications regarding the acceptability of organs and tissues for transplantation and to provide additional testing necessary for the overall evaluation of organ and tissue donor acceptability. In collaboration with the TK, he/she arranges the time to begin organ and tissue procurement. The BTK arranges the care of the deceased's body after collection. The BTK reports to the director of the health institution. The proposal to the Minister for the dismissal of the BTK may be submitted by the director of the health institution or by the NTK.

Article 9

PBTKs are appointed by the director of the health institution. PBTKs are team leaders in the tasks of taking and transplanting organs and tissues and tissue typing, as well as banks of organs, tissues or cells. They report to the BTK for:

- organization of preparation of possible recipients,

- organization of post-transplant monitoring of recipients,

- organization and support of explantation-transplantation teams,

- maintenance of contact with TKs during collection, selection of recipients and transplantation and

- other tasks on request by the BTK.

Article 10

This Ordinance shall enter into force on the eighth day following that of its publication in the Official Gazette.

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Reg. No.: 534-07-06-

1Zagreb, 11 April 2006

Minister
doc. dr. sc. Neven Ljubičić, vr

MINISTRY OF HEALTH

1252

Pursuant to Article 23, paragraph 2 of the Medical Organ Transplantation for Medical Purposes Act (Official Gazette 144/2012), the Minister of Health shall issue

RULES ON STANDARDS OF QUALITY AND SAFETY OF ORGAN TRANSPLANTATION

Article 1

This Ordinance determines the standards of quality and safety in human organ transplantation procedures for the purpose of treatment.

Article 2

This Ordinance transposes into the legal order of the Republic of Croatia Directive 2010/53 / EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 243, 16.9.2010).

Article 3

All healthcare professionals involved in donor preparation and assessment procedures, procurement, collection, testing and transplantation of organs must take all measures to ensure the quality and safety of organs for transplantation.

Organ procurement

Article 4

(1) Organ donation is an integral part of comprehensive medical care within the competence of intensive care units.

(2) All hospital health care institutions must put in place a quality system and the implementation of appropriate professional procedures and organizational measures for the efficient procurement of organs, in accordance with operational protocols and good clinical practice.

(3) The quality system referred to in paragraph 2 of this Article must include the development and supervision of the application of operational procedures for:

- optimizing the care of critical neurological patients and monitoring patients with severe brain damage

- timely recognition and system of quick notification of a possible donor

- cooperation with neurological and other departments and emergency admission

- determining brain death

- optimal care of a possible organ donor

- assessment of the characteristics and acceptability of a potential organ donor

- psychological approach to the family of the deceased

- reporting of serious adverse reactions and events

- quality assurance and control in the process of organ donation.

Article 5

(1) All units and departments caring for this type of patient must participate in the development of an operating procedure for optimizing the care of critical neurological patients and monitoring patients with severe brain damage.

(2) The operating procedure referred to in paragraph 1 of this Article must, inter alia, contain clinical triggers and activities that must be carried out by a doctor and / or a nurse in such a case. Such a concept of care that aims to optimize the management of critical neurological patients must include the possibility of organ donation as a medical reason for admitting a patient to an intensive care unit.

(3) The operating procedure must be available in writing, and its application in practice regularly monitored.

Article 6

(1) Optimal care of a potential organ donor must begin as soon as possible in order to increase the chances of successful organ procurement.

2) The optimal care of the donor is the responsibility of the doctor in the intensive care unit and is carried out in accordance with the national guidelines of the professional society for anesthesiology and intensive care, which include:

- hemodynamic maintenance, which includes monitoring and prevention of hypotension, hypertension, arrhythmia and cardiac arrest, and maintenance of arterial pressure, which guarantees adequate perfusion of organs,

- maintenance of electrolytes, which includes monitoring and correction of hypokalemia, hyperkalemia, hyponatremia and hypernatremia,

- maintaining body temperature above 35 ° C,

- maintenance of endocrine functions: which includes monitoring of clinical effects and prevention of changes in the hypothalamic-pituitary-thyroid axis and the hypothalamic-pituitary axis (diabetes insipidus) as well as changes in glucose metabolism,

- monitoring and correction of significant coagulopathies,

- adequate ventilation,

- maintenance of renal function with prevention of polyuria and oliguria.

Article 7

A specially trained coordination team is in charge of procuring organs. The responsibilities of the coordination team include:

- timely recognition and optimal care of potential donors

- verification of the List of Non-Donors,

- providing appropriate information to family members about the possibility of organ donation

- collecting data on the donor in the prescribed manner,

- assessment of the characteristics of the organ donor and submission of the prescribed data,

- keeping and submitting the prescribed documentation,

- informing the family that organs not accepted for transplantation will be destroyed,

- coordination of explantation teams and explantation procedure

- care for the donor's body in accordance with ethical principles

- report of serious adverse reactions

- quality control in the process of organ procurement

- communication with the National Coordinating Body

- educating staff and developing a culture of giving at the level of the institution and the region.

Donor identification

Article 8

(1) Before the start of explantation, at least one member of the explantation collection team is obliged to carry out the identification of the deceased donor.

(2) Verification of the identity of the donor must be entered in the records on the collection of organs, which must also contain the source of information for verification.

Feedback

Article 9

Upon completion of organ procurement, a feedback and letter of thanks should be sent to the donor hospital.

Organ packaging

Article 10

(1) The explantation team must provide all the necessary materials for packaging organs, tubes for biological samples, solutions and transport containers.

(2) The organ should be immersed in a suitable solution and stored in double or triple sterile packaging.

(3) The packaging material must be inert, impermeable and sterile.

(4) All packaging material must be licensed for its intended purpose, including maintaining the temperature within a certain range for a certain period of time.

(5) The outer container should provide thermal insulation and be made of a robust material to withstand leakage, shocks, pressure changes and other possible conditions during transport.

(6) Collected organs should have a label with all the necessary information, preserving the anonymity of the donor.

(7) Before being released for transport, it is mandatory to check the contents of the package and ensure the presence of all relevant information and documentation, together with appropriate labels.

(8) Organ transport containers must be marked with the following information:

- identification of the donor hospital, i.e. donor facilities, including address and contact telephone numbers,

- identification of the transplant center, including address and contact telephone number,

- the mark "HUMAN ORGAN", and the type of organ, with the inscription "HANDLE WITH CARE",

- recommended conditions of transport, including instructions on the appropriate temperature and position of the container,

(9) The organs must have DONOR INFO attached, in accordance with a special regulation, and a report on the explanted organ.

Organ transport

Article 11

(1) The time of organ transport should be kept to a minimum.

(2) The National Coordination Body in cooperation with Eurotransplant and the recipient's transplant center is responsible for the organization of appropriate transport.

(3) Organizations, bodies or companies involved in the transport of organs must have in place appropriate operational procedures and application of standards for the transport of biological samples which guarantee the integrity of the organs during transport and the appropriate transport time.

Organ transplantation

Article 12

(1) The quality standards for transplantation of program organs according to this Ordinance must include:

- one-year survival outcome of transplanted patients and grafts calculated by Kaplan-Meier method

- minimum standards of annual activity.

(2) The minimum standard of annual activity referred to in paragraph 1 of this Article means; 20 kidney transplants, 10 liver transplants, 8 pancreas transplants, 10 heart transplants, 5 lung transplants.

Article 13

The Ministry of Health provides the necessary information on the prescribed conditions for performing transplantation activities at the request of the European Commission or the Member States of the European Union.

Article 14

With the entry into force of this Ordinance, the Ordinance on safety and quality measures for parts of the human body for medical use (Official Gazette 143/2005 and 70/2009) shall cease to be valid in the part relating to organs.

Article 15

This Ordinance shall enter into force on the eighth day following that of its publication in the Official Gazette.

Class: 011-02 / 13-02 / 28

Reg. No.: 534-10-1-1-1 / 4-13-1

Zagreb, 15 April 2013

Minister

prof. dr. sc. Rajko Ostojić, Ph.D. med., vr

THE MINISTRY OF HEALTH

1253

Pursuant to Article 12, paragraph 3 of the Medical Organ Transplantation for Medical Purposes Act (Official Gazette 144/2012), the Minister of Health shall issue

RULES ON THE MANNER OF ASSESSING THE CHARACTERISTICS OF THE DECEASED DONOR FOR TRANSPLANTATION

Article 1

This Ordinance determines the procedures and manner of testing and assessment of the characteristics of the deceased organ donor for the purpose of transplantation.

Article 2

This Ordinance transposes into the legal order of the Republic of Croatia Directive 2010/53 / EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 243, 16.9.2010).

Article 3

Organs taken for the purpose of transplantation must be of acceptable quality and must not expose the recipient to unacceptable risk.

General assessment of organ donors

Article 4

(1) The general assessment of organ donors shall be performed in accordance with medical standards.

(2) All medical activities related to the selection and assessment of organ donors shall be carried out according to the advice and under the expert guidance of a doctor, the hospital transplant coordinator (hereinafter: coordinator).

(3) The general assessment of donor eligibility shall be performed on the basis of the assessment of medical documentation and data collected in intensive care units and interviews with the family or other relevant source, and must also include:

- a detailed assessment of medical history and data on risky behavior,

- clinical and external physical examination of the donor,

- laboratory tests and

- histological biopsy findings, in cases where previous levels of tests require it

- assessment of the autopsy findings (if performed).

(4) All donor eligibility assessment procedures must be documented and kept in the donor's medical documentation.

Medical history and behavioral data

For the purposes of assessing the medical history and data on donor behavior referred to in paragraph 3 of Article 4 of this Ordinance, data shall be collected in the manner prescribed by the Questionnaire for assessing the acceptability of organ and tissue donors, which is printed in Annex I to this Ordinance.

Clinical evaluation

(1) The coordinator is obliged to perform and document a detailed clinical examination, including external physical examination of the donor, before organ explantation, in order to determine signs of high-risk behavior, unexplained jaundice, hepatomegaly or jaundice, hepatitis or other infections, malignancies or signs of trauma.

(2) Clinical examination of the donor includes assessment of his hemodynamic status during maintenance, especially the occurrence of hypotension, duration of mechanical ventilation, days spent in the intensive care unit, the need for resuscitation and the use of inotropic and vasoactive drugs.

(3) Medical history, clinical, hemodynamic, biochemical and pharmacological parameters are needed to assess the general acceptability of a deceased person as an organ donor.

Laboratory tests

(1) For testing purposes, blood samples taken prior to cessation of blood flow are preferred. There must be a procedure to ensure identification and access to all stored samples.

(2) If the samples referred to in paragraph 1 of this Article are not available, blood samples for testing purposes must be taken as soon as possible after the cessation of blood flow, within 24 hours. To avoid hemolysis, samples must be centrifuged as soon as possible after collection.

(3) If the deceased donor received blood transfusions, blood products or infusions of colloidal or crystalloid compounds during the 48 hours before death, a blood sample taken prior to transfusion must be used for testing. If it is not available, an algorithm must be applied to assess hemodilution and to assess the risk of obtaining false-negative results from a blood-borne marker test, according to the sensitivity of the test method used.

(4) It is obligatory to carry out serological testing of donors for blood-borne diseases.

(5) Screening and confirmatory microbiological tests must be performed in a laboratory authorized to use approved testing techniques and accredited according to the current revision of the ISO 15 189 standard for the quality system in medical laboratories. Microbiological and serological tests are performed according to the valid Guidelines for the quality and safety of tissues and organs EDQM (Council of Europe).

(6) It is mandatory to perform the following minimum set of tests, which includes tests:

- HIV-1/2 antibodies,

- HBs antigen,

- HBc antibodies,

- HVC antibodies.

In special cases, additional tests may be needed, such as a syphilis test.

(7) When donating for an immunosuppressed recipient, additional tests must be performed:

- CMV antibodies,

- EBV antibodies,

- antibodies to toxoplasma.

(8) In donors living or coming from areas of high prevalence, it is mandatory to perform testing for HTLV1 antibodies, malaria, etc.

(9) Other tests depend on the organs to be transplanted and may include the following non-microbiological tests:

- typing of ABO blood groups and Rh (D) groups and human leukocyte antigen (HLA);

- complete blood count.

(10) All relevant biochemical tests must be carried out to assess the integrity and function of the graft.

(11) The laboratory must ensure long-term storage of the part of each sample from which the testing was performed, for at least 30 years.

General criteria for non-acceptance of donors

Article 5

General criteria for non-acceptance of donors are:

Transmissible diseases

- HIV, disease or seropositivity,

- active malignancy at any site, except for some primary and non-metastatic tumors of the central nervous system, basal cell carcinoma of the skin and cervical cancer in situ,

- a serious systemic infection that has not been treated or is of unknown origin,

- risk of prion disease transmission: donors treated with extracts from the human pituitary gland (growth hormone, etc.), with cases of Creutzfeldt-Jakob disease or similar transmissible spongiform (spongy) encephalopathy in the family or donors who have received a transplant of the human dura mater, cornea or sclera,

- viral hepatitis: organs from donors with HBsAg can be used for HBsAg-positive recipients, and organs from HCV-positive donors can be used for HCV-positive recipients (HCV PCR-positive). Furthermore, a donor who is HBsAg-negative but positive for HBc antibodies is acceptable as a donor if HBs antibodies are detected in his blood.

Behavioral risks

Behavioral risks related to HIV, HCV, HBV, and other communicable disease agents should be assessed by graft type and urgency.

Additional examinations during organ explantation

Systemic diseases, due to the specific effect they may have on grafts, sometimes require additional tests, and the final decision on organ acceptability depends on the macroscopic assessment of the explant surgeon and, if necessary, the histology of the organ biopsy.

Specific criteria for assessing the acceptability of individual organs

Article 6

The criteria for assessing the acceptability of organs are mainly based on the assessment of the appropriate function of the donor organ. The criteria may vary from center to center and may depend on the characteristics of the recipient. The criteria for assessing the acceptability of individual bodies are as follows:

a) Kidney

Age. There are no restrictions.

Previous illnesses. Attention should be paid to chronic hypertension, diabetes mellitus, albuminuria and kidney disease.

Renal function. Attention should be paid to urine volume, current and previous plasma creatinine values, creatinine clearance, urea, proteinuria, urine sediment, renal and ureteral ultrasound. In the case of chronic impairment of renal function, an attempt may be made to establish the cause by biopsy. Advanced, irreversible, chronic impairment of renal function is a contraindication for transplantation. Acute renal impairment of the donor may not necessarily be a contraindication, as it may be reversible.

Explanation and perfusion. Attention should be paid to the macroscopic appearance, color after perfusion, vascular changes, assessment of anatomical variations and atherosclerosis.

Postexplantation procedures. Organ biopsy may be required for evaluation in elderly donors and donors with vascular pathology, hypertension, diabetes, or cerebral hemorrhage of unknown cause. Mild histological changes with mild glomerulosclerosis and interstitial fibrosis may be acceptable.

b) Liver

Age. There are no restrictions.

Previous illnesses. Attention should be paid to previous viral liver diseases, liver diseases caused by alcohol or fat accumulation, surgical procedures in the hepatobiliary tract, uncontrolled abdominal infections, poisonings affecting liver function and liver injuries.

Liver function. Attention should be paid to the values of liver aminotransferases, serum bilirubin, alkaline phosphatase, LDH, albumin and coagulation tests. The significance of liver enzyme values must be interpreted considering the clinical picture.

Liver morphology. Liver ultrasound can be used to rule out clear fatty liver degeneration, cirrhosis and fibrosis, or any anatomical anomaly.

Explanation and perfusion. The liver macroscopically must be dark red (not pale or congested), soft, smooth surface and sharp edge. Vascular and anatomical changes and atherosclerosis must be assessed. It is equally important to assess liver color after perfusion. Visible fibrosis and cirrhosis or steatosis may be a contraindication for transplantation. A perioperative biopsy may be done to assess the degree of fatty degeneration. The degree of acceptability of fatty degeneration depends on the general condition of the donor and recipient and may vary, depending on the urgency of the recipient condition and the skill of the transplant team.

c) Heart

Age. Depending on local rules and the condition of the recipient.

Previous illnesses. Attention should be paid to previous heart disease (valve damage, ischemia, etc.), hypertension, diabetes mellitus, smoking, alcoholism, arteriosclerosis, hyperlipidemia, thoracic trauma, time spent in ICU, cardiorespiratory arrest, body surface area.

Search for acute myocardial ischemia. It must include tests of enzymes such as troponin, CPK, CPK-MB fraction, the values of which should be interpreted considering the clinical picture and the dynamics of the values. The ECG must be normal. Changes in atypical repolarization can be accepted in some circumstances.

Heart morphology. Ultrasound must assess the contractility and ejection fraction and the anatomy and function of the valves. If necessary, a chest X-ray and coronary angiography should also be considered.

Hemodynamics during donor resuscitation and maintenance. It includes blood pressure assessment, oxygen saturation, hemoglobin value, hypotension, cardiac arrest, administration and dosing of inotropic and vasoactive drugs, central venous pressure, and application of invasive hemodynamic measurement methods, if necessary.

Explanation and perfusion. It is necessary to pay attention to the macroscopic appearance, contractility and coronary palpation.

d) Lungs

Age. It depends on the individual assessment of the donor and recipient, and the skill of the teams.

Previous illnesses. Attention should be paid to previous lung diseases, smoking, active lung infections, aspiration, purulent secretion, thorax trauma and earlier thorax surgery.

Lung function. It must be assessed because if gas exchange and ventilation are not appropriate, the lungs are not suitable for transplantation.

Lung morphology. Röetgen thorax, bronchoscopy and CT of the thorax if necessary.

Explanation and perfusion. It is necessary to pay attention to the color of the lungs, the presence of atelectasis, tumors and appropriate insufflation.

e) Pancreas

Age. Depending on local rules.

Previous illnesses. It is necessary to pay attention to previous pancreatic diseases, alcoholism, diabetes mellitus, active abdominal infections, abdominal trauma, number of days spent in ICU, cardiorespiratory arrest, resuscitation procedures.

Pancreatic function. It can be assessed based on glucose and insulin needs, pancreatic enzyme values, calcium values. The significance of pancreatic enzyme values should be assessed in the light of previous diseases.

Pancreatic morphology. Ultrasound, MRI, or other imaging may be used in the assessment.

Hemodynamics. Severe hypotension or cardiac / pulmonary arrest severely impairs pancreatic quality.

Explanation and perfusion. Attention should be paid to the macroscopic appearance, vascular and anatomical changes, and satisfactory perfusion. There should be no severe edema or bleeding in the greater visible part of the pancreas. Peripancreatic hematomas and capsular lacerations are risk factors for graft pancreatitis.

f) Intestines

Application of general donor eligibility criteria

There are no established guidelines for donor selection although the number of bowel transplants is on the rise. Donors are preferably CMV negative, but if not, for CMV positive recipients, CMV positive donors may be considered.

Age. It depends on the transplant center protocol.

Previous illnesses. The criteria are the same as for selecting a liver donor, as most bowel transplants are also performed in the same act as a liver transplant. Donors must not be obese. There should be no history of alcoholism or uncontrolled abdominal infection, exposure to toxins affecting small bowel function, abdominal injuries, previous bowel disease, diarrhea, and should not be hospitalized for more than five days.

Hose function. The following should be considered: electrolyte values inclusive, sodium, potassium, then values of glucose, amylase, lipase, calcium. Also, complete blood count, albumin, protein,

coagulation test, liver function tests including LDH, GT, AF, bilirubin and aminotransferases. An assessment of bowel motility depending on the length of hospitalization, an assessment of hemodynamics during donor maintenance, and the use of vasoactive drugs with a vasoconstrictive effect must be performed.

Intestinal morphology. It can be assessed by abdominal ultrasound, to rule out ascites, other lesions and tumors, or by abdominal X-ray or endoscopy, if necessary.

Explanation and perfusion. Macroscopic appearance, intestinal peristalsis, vascular and anatomical changes, and satisfactory perfusion.

Article 7

(1) Data related to the procedure for assessing the characteristics of donors and organs must be collected in the manner prescribed by the DONOR INFO form printed in Annex II. of this Ordinance and forms an integral part thereof.

(2) Data listed in Part A of Annex II. of this Ordinance contain a minimum set of mandatory data, and the data listed in Part B of Annex II. of this Ordinance contain a set of supplementary data to be collected, based on the decision of the medical team or the request of the transplant recipient center.

(3) Notwithstanding paragraph 2 of this Article, if according to the risk and benefit analysis, including life-threatening emergencies, the expected benefits to the recipient outweigh the risks posed by incomplete data, the organ may be accepted for transplantation even in the absence of some mandatory data from Part A of Annex II. of this Ordinance.

(4) The hospital transplant coordinator of the donor institution shall be obliged to submit the data on the assessment of donor and organ characteristics to the National Coordination in electronic form without delay.

(5) The national coordination body shall be in charge of the delivery and exchange of data on the donor characteristics for the purposes of international cooperation and exchange of organs with Eurotransplant member countries.

(6) The final decision on the acceptability of organs for a specific recipient is made by the transplant center of the recipient. The Transplant Center is obliged to inform the National Coordination Body and Eurotransplant about its decision without delay in order to allocate organs efficiently.

Article 8

This Ordinance shall enter into force on the eighth day following that of its publication in the Official Gazette.

Class: 011-02 / 13-02 / 26

Reg. No .: 534-10-1-1-1 / 4-13-1

Zagreb, 15 April 2013

Minister

prof. dr. sc. Rajko Ostojić, MD,vr

ANNEX I

DONOR INFORMATION	
Name and surname of the donor	
date of birth	
Sex	
NTM number	
identification number	
ET number	

Code	**Question**	**Answer***		
		THAT	**NOT**	**NP**
1.	**INFECTIOUS DISEASES: Did the donor at the time of death have**			
1.a	acquired immunodeficiency syndrome (AIDS)			
1.b	active hepatitis			
1.c	encephalitis-viral or of unknown cause			
1.d	meningitis-viral or of unknown cause			
1.e	bacterial endocarditis			
1.f	progressive multifocal leukoencephalopathy			
1.g	acute sclerosing panencephalitis			
1.h	human T-cell lymphotropic virus infection (HTLV 1 and HTLV 2)			
1.i	other active infectious disease: tuberculosis, malaria, rabies, measles, scarlet fever, diphtheria, smallpox, typhus, leprosy (circle)			
1.j	protozoonosis (Q fever, brucellosis)			
1.k	other (specify)			
2.	**SYSTEMIC INFECTION: Did the donor have at the time of death**			
2.a	acute viremia			
2.b	acute systemic fungal infection			
2.c	bacteremia (specify causative agent)			
3.	**PRION TRANSFER RISK: Has the donor**			

3.a	suffered from Creutzeldt-Jakob disease or had the disease in the family			
3.b	suffered from progressive dementia with rapid development			
3.c	was treated with human growth hormone			
3.d	transplanted with human dura mater (dura mater)			
3.e	had previous neurosurgical operations without detailed medical documentation			
4.	**MALIGNANT DISEASES: Has the donor suffered from**			
4.a	leukemia			
4.b	lymphoma (Hodgkin's; non-Hodgkin's; lymphosarcoma, lymphomatoid granulomatosis)			
4.c	myeloma			
4.d	primary polycythemia of the faith			
4.e	malignant melanoma			
4.f	chorionic carcinoma			
4.g	other malignant diseases			
4.h	active malignancies at any location (except for some primary, non-metastatic central nervous system tumors as well as treated, rarely metastatic low-risk tumors)			
5.	**NEUROLOGICAL DISEASES: whether the donor has suffered from**			
5.a	chronic idiopathic demyelinating polyneuropathy			
5.b	amyotrophic lateral sclerosis			
5.c	multiple sclerosis Huntington's disease			
5.d	Guillain-Barré syndrome			
5.e	Alzheimer's disease or other dementias			
5.f	Parkinson's disease			
5.g	any degenerative or demyelinating diseases of the central nervous system			
6.	**RISK OF TRANSMISSION OF INFECTIOUS DISEASES: Has the donor:**			
6.a	had a degree of hemodilution that could give unreliable test results for markers of infectious diseases			
6.b	was in a chronic hemodialysis program			
6.c	long-term treatment with corticosteroids (≥10 mg / day / 4 years or ≥20 mg / day / 1 year)			
6.d	had a tissue and organ transplant			

6.e	had jaundice or hepatomegaly of unknown cause			
6.f.	was vaccinated with live vaccines within 4 weeks			
6.g	had hemophilia or another related disease and was treated with clotting factor concentrates			
6.h	took parenterally, intravenously, intramuscularly, subcutaneously drugs not prescribed by a doctor within 12 months			
6.i	was in close contact (same household) with a person who had viral hepatitis (except HVA)			
6.j	was exposed to HBV, HCV and HIV by percutaneous inoculation, via mucous membranes or injured skin within 12 months			
6.k	had a tattoo, piercing or acupuncture within 12 months (unless a disposable or sterile needle or equipment was used)			
6.l	ever been rejected as a blood donor (why)			
6.m	had gonorrhea or syphilis or was treated for these diseases within 12 months			
6.n	had sex for money or drugs within 12 months			
6.o	*only for men*: had sexual intercourse with a man within 12 months			
6.p	has been in prison for more than 72 hours within the last 12 months			
6.r	The child of a mother with HIV infection or a mother whose behavior is a risk factor for HIV infection (unless HIV infection can be safely ruled out in the child). Children under 18 months of age or who have been breastfed in the last twelve months should not be accepted as donors regardless of HIV test results.			
	Has the donor had sexual intercourse with a person in the last 12 months:			
6.s	who had sexual intercourse with a person infected with HIV or hepatitis B and C			
6.t.	took parenterally, intravenously, intramuscularly, subcutaneously drugs not prescribed by a doctor			
6.u	who was sexually active in areas of high incidence of HIV infection (HIV type 0)			
6.c	who had sex for money or drugs			
6.z	*If the donor is a woman: w*ith a man who had sex with a man			
7.	**TRAVEL: Has the donor**			
7.a	resided in the UK from 1986 to 1997 for more than 6 months			
7.b	traveled to countries with endemic communicable diseases such as malaria, trypanosomes, rabies, West Nile virus, etc. (www.CDC.gov)			
7.c	resided in an area with the presence of HIV subtype O			

8	**OTHER: Has the donor**			
8.a	suffered from a disease of unknown cause			

* YES, NO, NP - Unknown

Name and surname of the person who provided the data	Phone
Address:	
Kinship with the donor ☐spouse ☐child ☐parent ☐grandchild ☐grandparents ☐cousin ☐guardian	
I understood the questions and answered them as best I could. My answers are honest.	
Signature	Date

Name and surname of the coordinator	Signature	Date
Name and surname of the person who examined the medical records	Signature	Date

1.	**EYE: Did the donor have**			
1.a	uveitis (including systemic diseases: sarcoidosis, rheumatoid arthritis)			
1.b	congenital diseases and anomalies of the eye			
1.c	previous eyeball surgery, including eye tissue transplants (corneal, scleral, or lymph graft transplants)			
1.d	malignant diseases of the eyeball (retinoblastoma, melanoma)			
1.e	corneal dystrophy and keratoconus			

2.	**CARDIOVASCULAR SYSTEM: Did the donor have**			
2.a	endocarditis			
2.b	myocarditis			
2.c	rheumatic or other valvular heart disease			
2.d	congenital heart disease			
2.e.	coronary artery disease			
2.f.	dilated myocardiopathy			
2.g.	cardiac or thoracic trauma, especially puncture trauma (including intracardiac injection)			
2.h	cardiac resuscitation			
2.i	heart valve disease or surgery			

3.	**SKIN: Has the donor**			
3.a	had acute skin toxicity with known toxic chemicals, agents, and poisons			

3.b	autoimmune diseases and collagen tissue diseases (sarcoidosis, rheumatoid arthritis)			
3.c	was treated with radiotherapy or chemotherapy			
3.d	had a malignant mole			
4.	**MUSCLE-BONE SYSTEM: Did the donor have**			
4.a	localized irradiation, infection or acute intoxication (cyanide, lead, mercury or gold)			
* YES, NO, NP - Unknown				

Name and surname of the person who provided the data	Phone
Address:	
Kinship with the donor ☐spouse ☐child ☐parent ☐grandchild ☐grandparents ☐cousin ☐guardian	
I understood the questions and answered them as best I could. My answers are honest.	
Signature	Date

Name and surname of the coordinator	Signature	Date
Name and surname of the person who examined the medical records	Signature	Date

ANNEX II

DONOR INFORMATION - DONOR INFO

PART A

Minimum data group

Institution where organ donation takes place and other general information

Donor type

Blood type

Sex

Cause of death

Date of death

Date of birth or age estimate

Weight

Height

History of past or present intravenous drug use

History of past or present malignancy

Current history of other communicable diseases

HIV tests; HCV; HBV

Basic information for assessing the function of a donated organ

PART B

Supplementary data set

General Information

Contact details of the organization / institution where the explantation takes place, necessary for the coordination, allocation and traceability of organs from donor to recipient and vice versa.

Donor information

Demographic and anthropometric data needed to ensure appropriate coordination between donor / organ and recipient.

History of donor disease

Medical history of the donor, especially those conditions that could affect the suitability of organs for transplantation and that imply a risk of disease transmission.

Physical and clinical data

Data from clinical trials necessary to assess the physiological maintenance of a potential donor as well as any findings revealing conditions that remained undetected during the donor's medical history examination that could affect organ suitability for transplantation or could imply a risk of disease transmission.

Laboratory parameters

Data needed to examine the functional characterization of organs and to detect potentially transmissible diseases and possible contraindications for organ donation.

Imaging (radiological) examinations

Radiological examinations necessary to examine the anatomical status of the organ for transplantation.

Medicines

Therapy and drugs relevant to the examination of organ functional status and suitability for organ donation, in particular the use of antibiotics, inotropic support or transfusion therapy.

MINISTRY OF HEALTH AND SOCIAL WELFARE

2621

Pursuant to Article 10, paragraph 4 of the Act on the Taking and Transplantation of Parts of the Human Body for the Purpose of Treatment (Official Gazette 177/04), the Minister of Health and Social Welfare shall issue

RULES ON THE CONTENT OF THE CONSENT FORM OF THE RECIPIENT OF PARTS OF THE HUMAN BODY

Article 1.

This Ordinance determines the content of the consent form of the recipient of human body parts.

Article 2

The content of the consent form of the recipient of human body parts is set out in Annex I, which forms an integral part of this Ordinance.

Article 3

This Ordinance shall enter into force on the eighth day following that of its publication in the Official Gazette.

Class: 011-02 / 07-04 / 26
Reg. No .: 534-07-07-1

Zagreb, 23 July 2007

Minister
prof. dr. sc. Neven Ljubičić, vr

ANNEX I

CONSENT FORM OF THE RECIPIENT OF HUMAN BODY PARTS

I declare, of my own free will, based on all the information about the nature, purpose and course of the procedure, the likelihood of its success and the usual risks, my consent to receiving organs/tissues (specify organ/tissue to be received)

Healthcare institution

Organizational Unit

Place and date

Name and surname of the recipient

Date of birth of the recipient

Name and surname of the legal representative

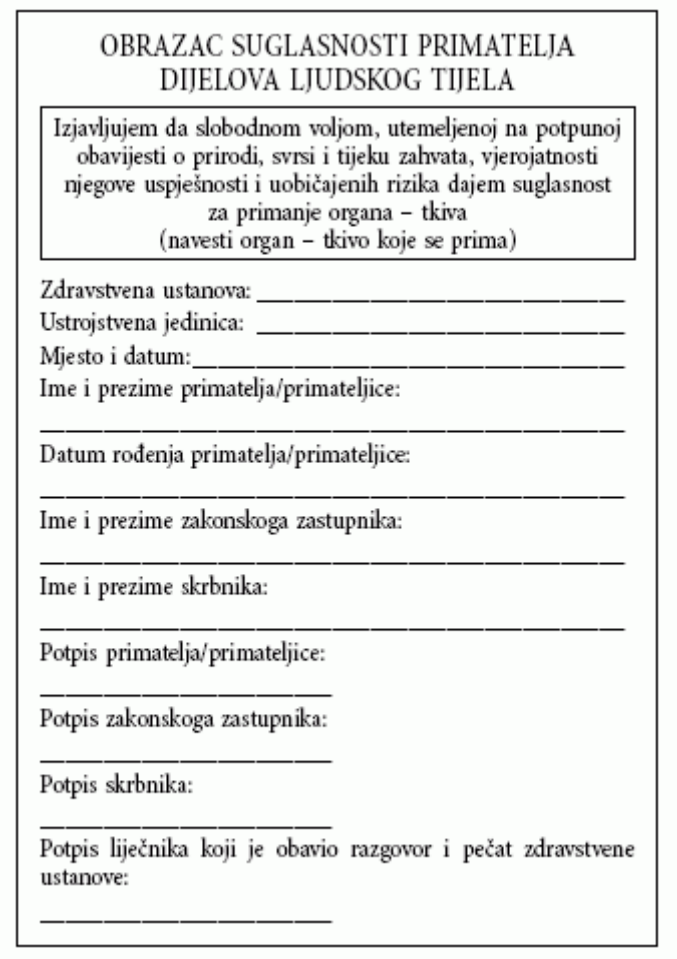
Name and surname of the guardian

Signature of the recipient

Signature of the legal representative

Signature of the guardian

Signature of the doctor who conducted the interview and the stamp of the health facility



OBRAZAC SUGLASNOSTI PRIMATELJA
DIJELOVA LJUDSKOG TIJELA

Izjavljujem da slobodnom voljom, utemeljenoj na potpunoj obavijesti o prirodi, svrsi i tijeku zahvata, vjerojatnosti njegove uspješnosti i uobičajenih rizika dajem suglasnost za primanje organa – tkiva
(navesti organ – tkivo koje se prima)

Zdravstvena ustanova: _____
Ustrojstvena jedinica: _____
Mjesto i datum:_____
Ime i prezime primatelja/primateljice:
_____
Datum rođenja primatelja/primateljice:
_____
Ime i prezime zakonskoga zastupnika:
_____
Ime i prezime skrbnika:
_____
Potpis primatelja/primateljice:
_____
Potpis zakonskoga zastupnika:
_____
Potpis skrbnika:
_____
Potpis liječnika koji je obavio razgovor i pečat zdravstvene ustanove:
_____

MINISTRY OF HEALTH AND SOCIAL WELFARE

2622

Pursuant to Article 17, paragraph 5 of the Act on the Taking and Transplantation of Parts of the Human Body for the Purpose of Treatment (Official Gazette 177/04), the Minister of Health and Social Welfare shall issue

RULES ON THE CONTENT OF THE CONSENT FORM OF A LIVING DONOR OF HUMAN BODY PARTS

Article 1.

This Ordinance determines the content of the form of consent of a living donor and the content of the form of revocation of consent of a living donor of parts of the human body.

Article 2

The content of the consent form of a living donor of human body parts is set out in Annex I, which forms an integral part of this Ordinance.

Article 3

The content of the form for revoking the consent of a living donor of human body parts is set out in Annex II. which forms an integral part of this Ordinance.

Article 4

This Ordinance shall enter into force on the eighth day following that of its publication in the Official Gazette.

Class: 011-02 / 07-04 / 27

Number: 534-07-07-1

Zagreb, 27 July 2007

Minister
prof. dr. sc. Neven Ljubičić, vr

ANNEX I

CONSENT FORM OF THE DONOR OF HUMAN BODY PART

Of my own free will, I declare that, on the basis of all the information about the nature, purpose and course of the procedure, the likelihood of its success and the usual risks, I consent to the donation of organs/tissues (specify organ/tissue to be donated)

Health institution

Organizational unit

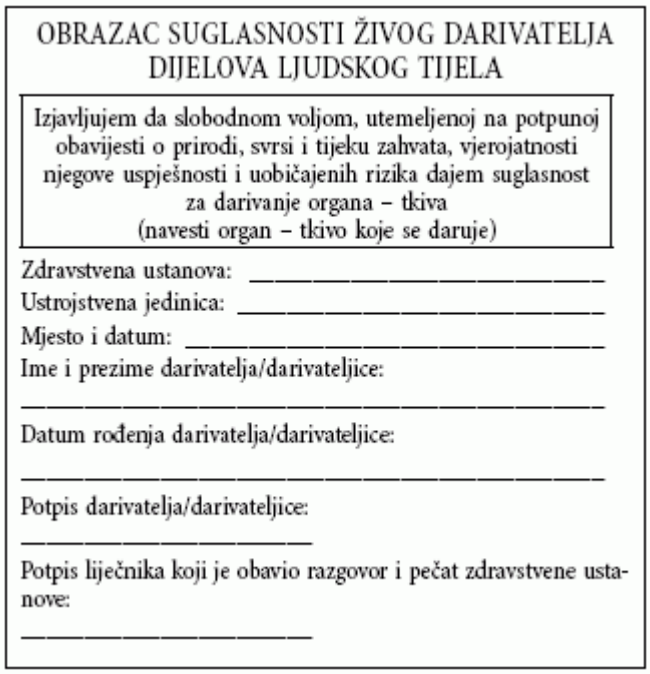
Place and date

Donor’s name and surname

Donor's date of birth

Donor’s signature

Signature of the doctor who conducted the interview and stamp of the health facility



OBRAZAC SUGLASNOSTI ŽIVOG DARIVATELJA DIJELOVA LJUDSKOG TIJELA

Izjavljujem da slobodnom voljom, utemeljenoj na potpunoj obavijesti o prirodi, svrsi i tijeku zahvata, vjerojatnosti njegove uspješnosti i uobičajenih rizika dajem suglasnost za darivanje organa – tkiva
(navesti organ – tkivo koje se daruje)

Zdravstvena ustanova: _____

Ustrojstvena jedinica: _____

Mjesto i datum: _____

Ime i prezime darivatelja/darivateljice:

_____

Datum rođenja darivatelja/darivateljice:

_____

Potpis darivatelja/darivateljice:

_____

Potpis liječnika koji je obavio razgovor i pečat zdravstvene ustanove:

_____

ANNEX II

FORM OF REVOCATION OF CONSENT OF A LIVING DONOR OF HUMAN BODY PARTS

I declare that, of my own free will, on the basis of comprehensive information about the nature, purpose and conduct of the procedure, I revoke the consent to the donation of organs/ tissues (specify organ/tissue)

Which I gave (specify date)

Healthcare institution

Unit

Place and date

Donor’s name and surname

Donor’s birth date

Donor’s signature

Signature of the doctor who conducted the interview and stamp of the health facility

OBRAZAC OPOZIVA SUGLASNOSTI ŽIVOG DARIVATELJA DIJELOVA LJUDSKOG TIJELA

Izjavljujem da slobodnom voljom, utemeljenoj na potpunoj obavijesti o prirodi, svrsi i tijeku zahvata, opozivam suglasnost za darivanje organa – tkiva
(navesti organ – tkivo)

Koju sam dao/dala (navesti datum) _____

Zdravstvena ustanova: _____

Ustrojstvena jedinica: _____

Mjesto i datum: _____

Ime i prezime darivatelja/darivateljice:

_____

Datum rođenja darivatelja/darivateljice:

_____

Potpis darivatelja/darivateljice:

_____

Potpis liječnika koji je obavio razgovor i pečat zdravstvene ustanove:

_____

MINISTRY OF HEALTH AND SOCIAL WELFARE

2670

Pursuant to Article 37, subparagraph 6 of the Act on the Taking and Transplantation of Parts of the Human Body for the Purpose of Treatment (Official Gazette 177/04), the Minister of Health and Social Welfare shall issue

RULES ON THE MANNER OF COOPERATION WITH RELATED FOREIGN AND INTERNATIONAL ORGANIZATIONS IN ORDER TO EXCHANGE ORGANS OR TISSUES FOR TRANSPLANTATION

Article 1

This Ordinance regulates the manner of cooperation of authorized health institutions referred to in Article 27, paragraph 1 of the Act on Taking and Transplanting Parts of the Human Body for Medical Purposes (hereinafter: authorized health institution) with related foreign and international organizations for the purpose of organ or tissue exchange for transplants.

Article 2

Cooperation for the purpose of organ or tissue exchange for transplantation is regulated by an agreement concluded by the ministry responsible for health and a foreign or international organization that performs organ or tissue exchange for transplantation.

Article 3

Any taking, transplantation and exchange of organs and tissues for the purpose of treatment, which is performed in the Republic of Croatia within the cooperation referred to in Article 1 of this Ordinance, must be reported to the ministry responsible for health, which shall keep records.

Article 4

An organ or tissue may be offered to a foreign country in the framework of the cooperation referred to in Article 1 of this Ordinance, only if there is no suitable patient on the national waiting list or if the exchange is based on obligations under the contract referred to in Article 2 of this Ordinance.

Article 5

Cooperation with related foreign international organizations for the purpose of exchange of hematopoietic stem cells is performed in accordance with a special regulation.

Article 6

The import of tissue from another country may be performed only by an authorized national tissue bank in accordance with a special regulation.

Imports referred to in paragraph 1 of this Article shall be permitted only from an internationally recognized and accredited tissue bank that ensures the quality and safety of tissues and with the approval of the Minister responsible for health.

Article 7

When exchanging tissue, the tissue bank ensures that the tissue meets quality and safety standards in accordance with a special regulation.

Article 8

When exchanging organs or tissues for the purpose of transplantation, it is not allowed to give or receive any money or other material goods.

Reimbursement of expenses for medical and organizational expenses related to the taking, storage and transportation of organs for the purpose of treatment is allowed.

Article 9

This Ordinance shall enter into force on the eighth day following that of its publication in the Official Gazette.

Class: 011-02 / 05-01 / 11
Reg. No.: 534-06-05-1
Zagreb, 17 November 2005

Minister
doc. dr. sc. Neven Ljubičić, vr

MINISTRY OF HEALTH AND SOCIAL WELFARE

2671

Pursuant to Article 37, subparagraph 8 of the Act on the Taking and Transplantation of Parts of the Human Body for Medical Purposes (Official Gazette 177/04), the Minister of Health and Social Welfare shall issue

RULES ON THE MANNER OF KEEPING PERSONAL DATA OF DONORS AND RECIPIENTS OF HUMAN BODY PARTS FOR THE PURPOSE OF TREATMENT

Article 1.

This Ordinance regulates the manner of storing personal data of donors and recipients of human body parts for the purpose of treatment.

Article 2

Personal data referred to in Article 1 of this Ordinance shall be collected, stored and communicated in accordance with special regulations governing the protection of professional confidentiality and the protection of personal data.

Article 3

The head of the personal data collection referred to in Article 1 of this Ordinance is the ministry responsible for health.

Article 4

Personal data referred to in Article 1 of this Ordinance shall be used, exchanged, processed and stored by authorized legal entities approved by the Minister of Health to perform a legally defined activity in the field of taking, transplanting and storing human body parts.

Article 5

Legal persons referred to in Article 4 of this Ordinance are obliged to ensure the authenticity, integrity and protection of personal data.

Article 6

Personal data or data from which it is possible to reveal the identity of the donor or recipient of human body parts shall not be disclosed, unless they are necessary for the performance of procedures in the field of taking and transplanting human body parts for the purpose of treatment.
Personal data must, as far as possible, be replaced by the identification code that the donor or recipient receives when registering and entering data into the information database.

Article 7

Legal persons referred to in Article 4 of this Ordinance may collect, process and store only those personal data that are necessary for that part of the activity of taking and transplanting parts of the human body that these legal persons perform.

Article 8

Personal data shall be exchanged between legal persons referred to in Article 4 of this Ordinance in a manner that prevents unauthorized persons from accessing personal data, their destruction, unjustified change and misuse.

Article 9

The use of personal data in pedagogical and scientific work, statistical analyses and publication of data from the field of taking and transplanting the human body for the purpose of treatment, must not be done in a way that could reveal the identity of the data subject.

Article 10

This Ordinance shall enter into force on the eighth day following that of its publication in the Official Gazette.

Class: 011-02 / 05-01 / 12
Reg. No .: 534-06-05-1
Zagreb, 17 November 2005

Minister
doc. dr. sc. Neven Ljubičić, vr

MINISTRY OF HEALTH AND SOCIAL WELFARE

2955

Pursuant to Article 37, subparagraph 5 of the Act on the Taking and Transplantation of Parts of the Human Body for Medical Purposes (Official Gazette 177/04), the Minister of Health and Social Welfare shall issue

RULES ON THE MANNER OF STORAGE AND TRANSPORT OF PARTS OF THE HUMAN BODY INTENDED FOR TRANSPLANTATION

Article 1.

This Ordinance regulates the manner of storage and transport of human body parts intended for transplantation from the place of collection to the tissue bank or authorized healthcare institution in accordance with Article 27, paragraph 1 of the Act on the Taking and Transplantation of Human Body Parts for Medical Purposes (hereinafter: the Act). and from a tissue bank to an authorized health facility.

Article 2

Terms in this Ordinance have the following meanings:

- *use*, when referring to organs, tissues and cells, means transplantation into the recipient's body, and when referring to biological samples, means laboratory analysis for the purposes of transplantation treatment;
- *storage* includes all procedures that ensure the preservation of the quality and biological function of parts of the human body from the moment of taking to use;
- *transport* is the process of transferring parts of the human body from the place of collection to the place of use;
- *standard operational procedures* (hereinafter: SOP) are detailed written instructions for the application of the rules of the profession in the storage and transport process;
- *tissue bank* is a healthcare institution which, based on the approval of the minister responsible for health, collects and stores tissues and cells;
- *donor center* is a healthcare institution in the Republic of Croatia or abroad, which performs the taking of organs, tissues and cells;
- *transplantation center* is a healthcare institution in the Republic of Croatia or another state that performs transplantation of a collected organ, tissue or cells;
- *National Transplant Coordinator* (hereinafter: NTK) is an authorized person at the Ministry responsible for health who organizes and supervises storage and transport
- *biological samples* (hereinafter: samples) are samples of human origin taken for the purpose of checking the immune and microbiological status of donors and recipients of human body parts, of determining tissue matching between donors and recipients and of quality control of laboratory work.

Article 3

Parts of the human body are transported in thermally insulated portable containers (hereinafter: carrier) made of hard material that prevents damage and leakage of contents. Carriers must have a carrying handle and must be secured during transport.

During transport, the carrier must not be exposed to direct sunlight.

The carrier must ensure that the temperature prescribed by the SOP is maintained.

Article 4

Parts of the human body are transported by the most appropriate and fastest means of transport, determined by the person responsible for storage and transport, with regard to the distance of transport and availability of means of transport, respecting the rules of the profession applicable to the storage of individual organs, tissues or cells.

Article 5

Transportation may be performed:
- by plane or helicopter
- the carrier is transported together with the crew's luggage, i.e. in the passenger compartment,
- by another appropriate means of transport, provided that the conditions referred to in Article 3 of this Ordinance are met.

Article 6

After collection, the human organ must be immersed in an appropriate solution and wrapped in two or three layers of sterile packaging material and stored in a carrier along with donor blood and tissue samples, according to the procedures defined by the SOP.
The carrier must be labelled with the inscription "HUMAN ORGAN - HUMAN ORGAN (in Croatian)", which contains:
- type of organ being transported,
- name and address of the donor center, telephone number and name and surname of the responsible person,
- flight data if the transport is performed by air, or the registration number of the vehicle if another means of transport is used,
- name and address of the transplant center, telephone number and name and surname of the responsible person,
- telephone number of the NTK at the ministry in charge of health
- instructions on transport conditions,
- instructions on safety measures for staff.
The carrier must be accompanied by documentation stating the identity of the donor (in the form of the assigned number) with information about the donor, mandatory microbiological tests, explanted organ and the date, time and place of collection of the organ.

Article 7

Organ transport is organized by the person who performed the explant or by the hospital transplant coordinator (hereinafter BTK) in agreement with the NTK, if the transport is organized without the escort of the explant team.
The NTK prepares the documentation necessary for the transport of organs across the state border and notifies the competent customs office, in writing, about the transport.
In the case of road transport across the state border, the NTK informs the Operational Communication Center of the Ministry of the Interior about the transport, in writing, which informs the competent police station at the planned border crossing about the transport.
When transporting organs across the state border, the NTK informs the Operational Communication Center of the Ministry of the Interior, the duty customs and police service at the airport and the airport security service about the transport, in writing.
The notification shall be made by telephone and fax with the form printed in Annex I, which forms an integral part of this Ordinance.

Article 8

If the organ transplant is performed in the Republic of Croatia, the transfer container with the organ is delivered to the transplant center and handed over to the responsible person in accordance with the instructions of the NTK.

The NTK or a member of the transplant team takes over the organ coming from abroad and hands it over to the responsible person referred to in paragraph 1 of this Article.

The manner of appointing the responsible person referred to in paragraph 1 of this Article shall be determined by the SOP by a healthcare institution that has the approval of the Minister for transplantation of human body parts. The healthcare institution shall submit the names of the responsible persons referred to in paragraph 1 of this Article to the NTK.

Article 9

Tissues and cells, after collection, must be sterile packaged and stored in carriers, according to the procedure defined by the SOP.

The carrier must have a label with the inscription "HUMAN TISSUE - HUMAN TISSUE (in Croatian)" which contains:

- type of tissue or cell,
- name and address of the donor center or tissue bank and name and surname and telephone number of the responsible person,
- flight data if the transport is performed by air or registration number if another means of transport is used,
- telephone number of the NTK at the ministry in charge of health,
- name and address of the transplantation center and name and surname and telephone number of the responsible person,
- the label "DO NOT RADIATE" in the case of hematopoietic stem cells (hereinafter KMS),
- instructions on transport conditions,
- instructions on safety measures for staff.

The transfer must be accompanied by documentation with the stated identity of the donor (in the form of the assigned number), and, in the case of a direct donation, with the identification of the recipient.

After closing, the carrier must not be opened and the tissue must not be removed until it is used or further processed.

Tissues and tissue cells can be transported and frozen. The transporter must maintain the appropriate temperature for 48 hours longer than the expected time of arrival at the destination (transplant center).

In the case of hematopoietic stem cell transfer for a recipient who has received high doses of cytostatics or whose whole body has been irradiated, transport must be provided accompanied by a person familiar with the risk of cell loss for the recipient.

The hematopoietic stem cell carrier must not pass through X-ray metal detection equipment.

Article 10

The person responsible at the donor center, i.e., the person responsible at the tissue bank, prepares all the necessary documentation for the transport of tissues or cells and organizes the transport of tissues.

The notification procedure for the transport of tissues across the state border shall be performed in the same way as the notification procedure for authorities in accordance with paragraphs 2 to 5 of Article 7 of this Ordinance.

The person responsible referred to in paragraph 1 of this Article shall be appointed by the donor center or tissue bank and the ministry in charge of health shall be informed.

Article 11

Biological Samples, after collection, must be packaged and stored in a carrier, in accordance with the procedure defined by the SOP, with respect to the type and purpose of the sample taken.

The carrier must bear a label marked "BIOLOGICAL SAMPLE OF HUMAN ORIGIN" containing:

- type of sample,
- name and address of the sender,
- name and address of the recipient.

The carrier must be accompanied by documentation stating the identity of the donor (in the form of the assigned number), data on the sample taken and the day, place and time of sampling.

The enclosed documentation and the designation of the carrier must specify the special conditions for handling the container.

Article 12

The person responsible at the healthcare institution where the sampling was performed prepares the entire documentation for transport within the Republic of Croatia.

The person responsible at the healthcare institution referred to in paragraph 1 of this Article shall prepare the entire documentation and agreement with the NTK transport of samples across the state border. The notification procedure for the transport of a biological sample across the state border shall be performed in the same way as the notification procedure for authorities in accordance with paragraphs 2 to 5 of Article 7 of this Ordinance.

A carrier for transport across the state border must have documentation containing:

- name and address of the sender,
- name and address of the recipient,
- telephone number of the NTK at the ministry in charge of health
- purpose of taking or sending a sample,
- quantity and type of sample,
- a statement by the consignee obtained by the consignor that the samples will be used in their entirety during testing only for the purpose for which they were taken, that they are not infectious or toxic and that they have no commercial value.

The person responsible referred to in paragraph 2 of this Article shall be appointed by the healthcare institution that performs laboratory analyses and the ministry in charge of health shall be informed.

Article 13

The following information must be kept during transport:

- identification of persons responsible for dispatch and receipt,
- identification of accompanying persons,
- date and time of dispatch of organs / tissues / cells,
- all information on delays and adverse events during transport,
- date and time of admission of organs / tissues / cells to the transplant center / tissue bank.

Article 14

On the day, this Ordinance enters into force, the provisions of the Ordinance on data and the manner of keeping documentation on possible donors of human body parts for transplantation from a deceased person (Official Gazette 188/03) shall cease to apply in the part relating to the manner of storage and transport of human bodies intended for transplantation.

Article 15

This Ordinance shall enter into force on the eighth day following that of its publication in the Official Gazette.

Class: 011-02 / 05-10 / 3
Reg. No.: 534-6-05-1

Zagreb, 16 December 2005

Minister
doc. dr. sc. Neven Ljubičić, vr

ANNEX I

REPUBLIC OF CROATIA Ministry of Health and Social Welfare Zagreb, Ksaver 200a Tel: 01 4607 555 Fax: +385 1 4677 105	Customs office _____ MUP Operational Communication Center _____ Airport Security Service _____

CONFIRMATION

ON THE TRANSFER OF THE HUMAN ORGAN / TISSUE
FROM / TO THE REPUBLIC OF CROATIA
EXCLUSIVELY FOR THE PURPOSE OF TRANSPLANTATION

☐ Transfer of the transplant team with medical equipment and transfer of a human organ
☐ Human organ / tissue transfer for transplantation purposes
- unaccompanied
- with an escort
☐ To (State)
☐ From (State)
☐ Type of means of transport (mark) _____
☐ Arrival time date: _____hour: _____
☐ Departure time date: _____hour: _____
☐ Number of transplant team members _____
☐ Number and type of organs / tissues _____
☐ Identification of the vehicle authorized by the Ministry of Health and Social Welfare participating in the transport
_____
☐ Name and surname of the authorized person participating in the transport_____
The human organ / tissue will be used exclusively for the purpose of transplantation and will not be subject to material or other benefits.
Zagreb, on _____
National Transplant Coordinator
MP Name and surname _____
Signature _____
Phone: _____

MINISTRY OF HEALTH AND SOCIAL WELFARE

2957

Pursuant to Article 37, paragraph 1 of the Act on the Taking and Transplantation of Parts of the Human Body for the Purpose of Treatment (Official Gazette 177/04), the Minister of Health and Social Welfare shall issue

RULES ON THE PROCEDURE OF NOTIFYING THE DEATH OF PERSONS CONSIDERED AS DONORS OF PARTS OF THE HUMAN BODY FOR TRANSPLANTATION FOR THE PURPOSE OF TREATMENT

Article 1.

This Ordinance establishes the procedure for notifying the death of persons who are considered as donors of human body parts for transplantation for the purpose of treatment.

Article 2

For the purposes of this Ordinance, parts of the human body shall mean organs and tissues.

Article 3

For each patient in the intensive care unit of a hospital/healthcare institution (hereinafter: ICU), the attending physician or the doctor on duty must immediately fill in the form "Report of a patient in a coma", if the patient meets the following conditions:

- coma patient with Glasgow coma scale 7 and established coma etiology:

craniocerebral injury,
stroke,
decompensated primary intracranial tumor,
anoxic brain damage,
inflammation of the central nervous system.

The form referred to in paragraph 1 of this Article is printed in Annex I to this Ordinance and forms an integral part of it. The form shall be completed in two copies, one of which shall be attached to the medical history, and the other copy shall be submitted electronically or by another appropriate means to the hospital transplant coordinator (hereinafter: BTK), within no more than 6 hours.

Article 4

A doctor in the ICU who has admitted a patient in a coma according to the criteria referred to in Article 3 of this Ordinance must, in accordance with medical criteria, performs clinical procedures to determine brain death and immediately notify the BTK of the findings.

Article 5

In hospitals/health facilities that do not have the possibility to complete the brain death confirmation procedure, doctors are obliged to begin the brain death diagnosis procedure in accordance with medical criteria and to arrange for the arrival of a mobile brain death confirmation team, if available, with the national transplant coordinator (hereinafter NTK) or to provide the transportation of the patient to a health facility where a brain death confirmation procedure can be performed.

In the case of the transport of the patient, the form of the report on the determination of death should be attached to other medical documentation of the patient which is submitted to the health institution referred to in paragraph 1 of this Article.

Article 6

After a brain death has been established, the BTK must notify without delay the NTK of the possible donor in order to verify the status of the deceased in the List of Non-Donors.

If the deceased is not on the List of Non-Donors, the BTK notifies the family of the deceased of the intention to transplant body parts for the purpose of treatment.

Article 7

Immediately after fulfilling the prescribed conditions for organ donation, the BTK must submit to the NTK at a minimum the following information on the possible donor:

- name and surname,
- date of birth,
- cause and time of death,
- a brief history of the disease,
- hemodynamic status,
- blood type.

The completed form "Donor data - Donor info", which is printed in Annex II. of this Ordinance, and a copy of the blood type must be submitted by the BTK to the NTK in writing, electronically or in another appropriate mannerwithin 60 minutes.

Article 8

A doctor who has determined the death of a patient in a hospital/ medical institution outside the intensive care unit shall inform the person responsible for tissue collection.

Article 9

The doctor referred to in Article 8 shall complete for each deceased person the "Tissue donation"form , which is printed in Annex III. of this Ordinance and forms an integral part of it.

The form referred to in paragraph 1 of this Article shall be completed in two copies, one of which shall be attached to the medical history, and the other shall be handed over to the person responsible for tissue collection.

The person responsible for tissue collection is appointed by the director of the hospital/ health facility.

Article 10

The person responsible for collecting the tissue checks whether the deceased person is on the List of Non-Donors before the tissue explantation procedure.

If the deceased is not on the List of Non-Donors, the person responsible for tissue collection shall ensure that tissue collection procedures are carried out, including informing the deceased's family of the intention to transplant the tissue for medical purposes.

Article 11

If the deceased is on the List of Non-Donors, all further procedures for the purpose of organ and / or tissue donation shall be suspended.

Article 12

On the day, this Ordinance enters into force, the provisions of the Ordinance on data and the manner of keeping documentation on possible donors of human body parts for transplantation from a deceased person (Official Gazette 188/03) shall cease to apply in the part relating to the notification of deaths of persons who come into consideration as donors of human parts for transplantation for medical purposes.

Article 13

This Ordinance shall enter into force on the eighth day following that of its publication in the Official Gazette.

Class: 011-02 / 05-04 / 16
Reg. No.: 534-06-05-1
Zagreb, 16 December 2005

Minister
doc. dr. sc. Neven Ljubičić, vr

ANNEX I

_____
Name of health institution

_____
Intensive care unit

REPORT OF PATIENT IN COMA
for every patient admitted to the ICU in a coma who does not breathe on his own and needs support
of mechanical ventilation and who has been diagnosed on admission (circle):

AND. 1. isolated craniocerebral injuries or
2. stroke or
3. decompensated intracranial tumor or
4. anoxic brain damage or
5. inflammation of the central nervous system

B. registration number of medical history

C. initial letters of names and surnames □□□□

D. sex F □ M□

E. year of birth □□□□

F. date of admission □□ □□ □□
day month year

Mr. day and hour of introduction of respiratory support □□ □□ □□
day month year
□□ □□
hr min

H. Name, surname and facsimile of the doctor
_____

AND. Notice to hospital coordinator _____
Day Hour

J. Hospital Coordinator / Deputy Informed _____
Signature

ANNEX II

1/2

DONOR INFORMATION									
DONOR -INFO					Date:			Hour:	
Name and surname:				Number of donors	ABO Rh:	Date of birth:		Age:	Sex:
Height:			Weight:			Thorax circumference:		Abdominal circumference:	
		cm			kg		cm		cm
TT lab	AND	AND	AND	AND	B	B	B	B	
	Bw	Bw	Cw	Cw					
TT material	DR	DR	DR	DR	DR	DR			
	DQ	DQ	DQ	DQ	Cw	Cw			
HOSPITAL				CIRCULATION					
Hospital:				Diuresis:	Last hour:		Jr.		
Phone:					Last 24 hours:		Jr.		
Contact person:					Last _____ hours:		Jr.		
Phone:				Blood pressure:	mm / Hg				
Brain death	Date:		Time:	CVP:	cmH2O / mmHg				
Permission for explantation		YES	NO	Hypotensive episodes:	R. no.	Date	min.	mm Hg	
					1.				
Explantation planned:					2.				
					3.				
Date: October 7, 2003		Time:		Cardiac arrest:	YES NO	Date		min.	
				Resuscitation:	YES NO	Date		min.	
Organs explanted by the local team:				Notes:					
Heart	Lungs	Liver	Kidneys						
Pancreas				**VIROLOGY / BACTERIOLOGY**					
ADMISSIBILITY FOR TRANSPLANTATION (if NOT why)				anti HIV 1, 2			HBsAg		
				anti HBs			anti HBc		
Heart	YES NO			anti HCV			VDRL / TPH		

			TOXO IgM			TOXO IgG		
			CMV IgM			CMV IgG		
Lungs	YES NO		Other:					
Liver	YES NO		**MICROBIOLOGICAL CULTURES**					
			Urine:					
Pancreas	YES NO		Sputum:					
			Blood:	1.				
R-Kidney	YES NO			2.				
				3.				
L-Kidney	YES NO		**MEDICATION**					
			Dopamine:				mcg / kg / min	
GENERAL CLINICAL PARTICULARS			Dobutamine:				mcg / kg / min	
Cause of death:			Adrenaline:				mg / h	
			Noradrenaline:				mg / h	
			Other inotropes:					
Admission to the hospital:	Date:	Hour:						
Admission to the ICU	Date:	Hour:	Blood transfusion from admission:					Jr.
Respirator	Date:	Hour:	Blood transfusion last 24 h:					Jr.
Urinary catheter	Date:	Hour:	Plasma expanders u last 24 hours:	R. no.	Name			
				1.				Jr.
				2.				Jr.
Temperature		˚C		3.				Jr.
ANAMNESIS			Other drugs:					
Hypertension	YES NO							
Diabetes m.	YES NO							
Smoking:	YES NO	Year:	Box:					
Alcohol:	YES NO	Year:						
Drugs:	YES NO		Notes:					

Other:	

ANNEX II.2 / 2

DONOR INFORMATION							
DONOR-INFO					Date:		
Name and surname:		Number of donors	ABO Rh:		Date of birth:	Age:	Sex:
LABORATORY DIAGNOSTIC					X-ray	ECG	UZV
BLOOD					**Chest X-ray 1**		
Test	DAY / HOUR	DAY / HOUR	DAY / HOUR				
Erythrocytes				x1012 / L			
Hb				mmol / L			
Ht				%			
Leukocytes				x103 / L			
Platelets				x103 / L			
On				mmol / L			
K				mmol / L	**ECG**		
Glucose				mmol / L			
CPC				U / L			
CK-MB				U / L			
Troponin 1				U / L			
Troponin T				U / L			
AST				U / L			
ALT				U / L			
LDH				U / L	**UZV**		
gamma GT				U / L			
PV				sec.			
APTV				sec.			
Albumin				g / L			
Urea				mmol / L			

Creatinine				Humol / L
Fibrinogen				g / L
Bilirubin uk.				Humol / L
Bilirubin dir.				Humol / L
Total proteins.				g / L
Alk.phosphatase				U / L
Amylase				U / L
Lipase				U / L
URINE	GUK		Albumini	
ACIDO-BASE STATUS				
SEARCH	DAY / HOUR	DAY / HOUR	DAY / HOUR	
			/	
FiO2 (%)			100%	
PEEP			5cm H2O	In 10 min.
ph				
pCO2				mmHg / kPa
pO2				mmHg / kPa
HCO3				mmol / L
BE				mmol / L
O2 hour.				%
PULMONARY LIMITS				
Right apex to right FCC				cm
Left apex to left FKK				cm
Right FKK to left FKK				cm
Right apex to diaphragm				cm
Left apex to diaphragm				cm

OTHER DIAGNOSTICS	
NOTES	

Submit to the Ministry of Health and Social Welfare National Transplant Coordinator tel .: 00385 (98) 404-946 (0-24); Fax: 00385 (1) 4677-105

ANNEX III

Health institution: Department:
....
_____

TISSUE DONATION
(completed in duplicate)

DECEASED PERSON
Surname..... Given name.....
Date of birth .....
MBG .....
Completed by the doctor when determining the death:
Time of death: Date:..... Hour:.....
Cause of death: ....
Natural death: YES NO
Would the deceased be an appropriate tissue donor? YES NO
- If the answer is no, why not? ....
- If acceptable to be a donor, notify the person responsible for tissue collection
YES NO
The person responsible for tissue collection was informed: YES NO
Date: .....
Given name and surname of the doctor Signature
.... ……

MINISTRY OF HEALTH AND SOCIAL WELFARE

3245

Pursuant to Article 23, paragraph 2 of the Act on the Taking and Transplantation of Parts of the Human Body for the Purpose of Treatment (Official Gazette 177/04), the Minister of Health and Social Welfare shall issue

RULEBOOK ON THE CONTENT, MANNER AND PROCEDURE OF SUBMITTING THE FORM AND MANNER OF KEEPING RECORDS AND PROCEDURE FOR WITHDRAWAL OF THE STATEMENT OF NON-DONATION OF BODY PARTS FROM THE DECEASED

Article 1

This Ordinance regulates the content of the form, the manner and procedure of delivery, the manner of keeping records and the procedure of revoking statements of non-donation of body parts from a deceased person for transplantation for medical purposes. The completed statement referred to in paragraph 1 of this Article shall be stored and maintained by the Ministry of Health and Social Welfare (hereinafter: the Ministry).

Article 2

An adult capable of reasoning who opposes the donation of body parts after death gives a written statement of non-donation of body parts after death to the selected primary care physician with the form "Statement of non-donation of body parts after death" (hereinafter: Statement) printed in Annex I to this Ordinance and forms an integral part of it. For adults who are incapable of reasoning, a written statement of non-donation solemnized by a notary public shall be given to the elected primary care physician by that person's legal representative or guardian. A blind person, deaf person who can't read, a mute person who cannot write and a deafblind person, gives a statement of non-donation in the form of a notarial deed or a statement on the appointment of a legally capable person who will give a non-donation statement on his behalf.

Article 3

The Statement form contains the following information:

- Given name and surname,

- date of birth,

- sex,

- place of birth,

- residence address,

- identification number of the insured person in compulsory health insurance,

- code of the selected doctor of primary health care,
- statement expressing opposition to the donation of organs and tissues, only organs or only tissues,

- unique identification number,

- signature and facsimile of the primary care doctor,

- place and date of completion of the Statement (day, month, year),

- handwritten signature of the Statement provider.

Article 4

The declaration shall be completed in triplicate. The first copy shall be delivered by the selected doctor of primary health care immediately after signing, and no later than three days from signing, by mail, to the Ministry in a special envelope. The second copy is stored in the documentation of the selected primary care physician, and the third copy is given to the signatory of the Statement.

Article 5

The received written Statement is stored in the Ministry, and the data from the Statement are entered into a single database of the List of Non-Donors (hereafter: the List).

Article 6

The authorized person who has the right to access the data from the List is obliged to confidential all data accessed in the List. The data from the List can be used only for the official search of the List and for the production of aggregate statistical indicators.

Article 7

An authorized person by searching the List may obtain the following information:

1. number of valid and invalid Statements,

2. number of newly registered Statements in a certain period,

3. number of revoked Statements,

4. number of performed official searches,

5. given name and surname of the authorized person who performed the official search,

6. other information requested by an authorized person.

Article 8

Special regulations on the protection of personal data shall apply to individual data collected on the basis of this Ordinance.

Article 9

The signatory of the Statement may revoke his Statement at any time. The Statement shall be revoked by filling in the form "Revocation of the statement of non-donation of body parts after death" (hereinafter: Revocation of the non-donation statement) printed in Annex II. of this Ordinance and which forms an integral part of it. The elected doctor of primary health care shall submit the Revocation of the non-donation statement to the Ministry in the manner prescribed by Article 4 of this Ordinance.
Upon completion of the Revocation of the statement, the signatory is deleted from the records of valid non-donors and data on the changed status is updated in the records of the List of Non-Donors.

Article 10

This Ordinance shall enter into force on the eighth day after its publication in the Official Gazette.

Class: 543-02 / 05-01 / 16
Reg. No.: 534-05-02 / 1Zagreb, 16 October 2007

Minister
prof. dr. sc. Neven Ljubičić, vr

ANNEX I

MINISTRY OF HEALTH AND SOCIAL CARE

STATEMENT OF NON-DONATION OF BODY PARTS AFTER DEATH

Unique identification number: _____
(to be completed in triplicate in CAPITAL LETTERS)

Given name and surname _____

Date of birth _____

Sex M F

Place of birth _____

Address of residence _____
insurance _____

Code of the chosen doctor of primary health care _____

I oppose donating
(circle): 1. Organs and tissues 2. Organs 3. Tissues

Place and date: _____

Handwritten signature of the donor Statement: _____

Signature and facsimile of the selected primary care physician _____

The selected Statement shall be submitted by the primary care physician in written form, immediately upon signing, and no later than within 3 days, to the Ministry of Health and Social Welfare, Ksaver 200a, Zagreb. The statement is delivered by registered mail in a special envelope with the printed address of the Ministry of Health and Social Welfare. The second copy of the Statement is stored in the documentation of the selected primary care physician, and the third copy is given to the signatory of the Statement. For additional information, please call the toll-free number of the Ministry of Health and Social Welfare: 0800 200 063 (weekdays from 8:00 to 16:00).

ANNEX II

MINISTRY OF HEALTH AND SOCIAL CARE

REVOCATION OF THE STATEMENT OF NON-DONATION OF BODY PARTS AFTER DEATH

Unique identification number: _____
(to be completed in triplicate in CAPITAL LETTERS)

Given name and surname _____

Date of birth _____

Sex M F

Place of birth _____

Address of residence _____

Identification number of the insured person in the compulsory health insurance
_____

Code of the selected doctor of primary health care _____

I revoke the Statement of non-donation of body parts after death number: _____

Place and date: _____

Handwritten signature of the donor Statement: _____

Signature and facsimile of the selected doctor of primary health care
_____

The Written Revocation of the Statement shall be submitted by the selected primary care physician immediately upon signing and no later than within 3 days to the Ministry of Health and Social Welfare, Ksaver 200a, Zagreb. The revocation of the Statement shall be delivered by registered mail in a special envelope with the printed address of the Ministry of Health and Social Welfare. The second copy of the Revocation of the Statement is stored in the documentation of the selected doctor of primary health care, and the third copy is given to the signatory of the revocation of the Statement. For additional information, please call the toll-free number of the Ministry of Health and Social Welfare: 0800 200 063 (weekdays from 8:00 to 16:00).