



Republika e Kosovës
Republika Kosovo - Republic of Kosovo
Kuvendi - Skupština - Assembly

Law No. 04/L-192

ON TRANSPLANTATION OF TISSUES AND CELLS

Assembly of Republic of Kosovo,

Based on Article 65 (1) of the Constitution of the Republic of Kosovo,

Approves

LAW ON TRANSPLANTATION OF TISSUES AND CELLS

CHAPTER I
GENERAL PROVISIONS

Article 1
Purpose

1. This law determines the conditions and rules for transplantation of tissues and cells in the field of human medicine.
2. This Law regulates the procedures, based on which, the ethic committee, the tissue and cell banks, the health institutions, other bodies and authorized persons shall act in matters concerning the transplantation of tissues and cells.
3. This Law does not regulate:
 - 3.1. transplantation of organs;

- 3.2. blood donation, transfusion of blood and blood components;
- 3.3. assisted reproduction.

Article 2

Scope

This Law shall be applied in healthcare institutions exercising health activities in the field of tissue and cell transplantation.

Article 3

Definitions

1. The terms used in this Law shall have the following meanings:

1.1. **Transplantation** - the set of medical measures and other activities related to the removal of tissues and cells from a living person or a human corpse and their implantation in another person for therapeutic purposes.

1.2. **Transplantation** - the placement of the transplant within the same individual, individuals of the same species, individuals of different species and identical individuals from the genetic point of view, which is implemented for medical needs only and when it is assessed to be indispensable to assure the life and health of the recipient of the transplant.

1.3. **Transplantation** - the implantation of hematopoietic cells and tissues and embryonic cells.

1.4. **Transplantation** also includes the proceedings related to supply, expertise, processing, preserving and permission of certain tissues and cells to be used in the field of human medicine.

1.5. **Transplants** - the tissues and cells of human and animal origin intended for implantation into the human body.

1.6. **Allogeneic transplants** - tissues and cells that are donated by one person and are used in another person, who is in need of them.

1.7. **Autologous transplants** - the removal of tissues or cells from one person and their implantation into the body of the same person for therapeutic purposes.

1.8. **Testing** - the set of laboratory examinations conducted on the transplants or the donor.

1.9. **Treatment** - the preparation activity for removing tissues and cells for implantation purpose through the application of physical, chemical or biological methods during their removal or immediately after their removal, including the packaging and conservation without affecting their integrity or physiological conditions.

1.10. **Reasonable term** - the period, during which, the tissues and cells maintain their vitality and can be used for transplantation.

1.11. **Application in Humans** - the use of tissues and cells in the human body.

1.12. **Expertise** - the activity related to the research for assessing the condition of tissues and/or donor cells, in order to establish the immunization condition, the presence of a disease in the organism, the presence of chemical or biological substances by which a disease, infection or intoxication may be transferred

1.13. **Distribution** - the transportation and delivery of tissues and cells intended for application in humans.

1.14. **Donation** - the procedure of donating human tissues and cells, intended for application in humans.

1.15. **Donor** - a person, alive or dead, from whom tissues and cells were taken to be implanted into a person needing them.

1.16. **Living donor** - the individual from whom the tissue and cell was taken to be implanted in another person for therapeutic purposes.

1.17. **Tissues** - all parts of the human body formed by cells.

1.18. **Implantation** - the placement by medical methods of tissues and cells in the body of the recipient.

1.19. **Embryonic tissues and cells** - the tissues and cells that are taken from the body of the human embryo.

1.20. **Self-generating tissue** - the tissue which can re-generate its mass, after a part of it has been taken

1.21. **Removal** - the removal of tissues and cells from the body of the donor using medical methods for the purpose of implantation or therapeutic, diagnostic and scientific needs.

1.22. **Procurement** - the process, through which the tissues and cells are made available.

1.23. **Conservation** - the use of chemical or biological substances, modification of environmental conditions or the use of other means during the processing phase in order to preserve the structure or prevent the degradation of human tissues and cells.

1.24. **Quarantine** - the condition when the removed tissues and cells are isolated physically or by other effective means, while awaiting the decision on their acceptance or rejection.

1.25. **Quality management** - the coordinated activity to manage and control a subject regarding quality.

1.26. **Ministry** - the Ministry of Health.

1.27. **Health Institution for Transplantation of Tissues and Cells** – health structures, tissue and cell banks, hospital units or other body that deals with proceeding, conservation, preservation or distribution activities of collected tissues and cells. It may, also, be responsible for procurement and testing of tissues and cells.

1.28. **Waiting patient** - the person registered in the registry of people waiting for the realization of the implantation of the transplant.

1.29. **Recipient** - the person who has received a tissue or the cells from the transplantation process.

1.30. **Processing** - the procedure for the preparation, treatment and packaging of tissues and cells intended for transplantation.

1.31. **Packaging** - the proper isolation of tissues and cells using proper material in order to prevent them from damage or contamination.

1.32. **Standard operational procedures** - the instructions in writing, which determine the action procedures and include the materials to be used and the expected results.

1.33. **Cell for Transplantation** - the individual human cell or a group of human cells, which do not form any kind of a connective tissue.

1.34. **Hematopoietic cells** - the “parent” cells, from which there are derived further blood cells.

1.35. **Placental cells** - the cells that derive from the placenta.

1.36. **Brain death or cerebral death** - the irreversible loss of the function of the whole brain, including its cells.

1.37. **Biologic or cell death** - the real death, whereby the activity of all vital systems, cells and tissues as well as the metabolic activity of the whole organism cease to work permanently.

1.38. **Quality system** - the organizational structure, the responsibilities, procedures, processes and sources set forth for the implementation of the quality management and includes all the activities contributing to the quality, either directly or indirectly.

1.39. **Distribution** - the transporting and delivery of tissues and cells intended to be used for implantation.

1.40. **Labeling** - the activity related to the noting of information on packaged tissues and cells in order to identify them.

1.41. **Preservation** - the storing of transplants in adequate conditions in order to not damage them or their packaging, controlled up to the moment of their distribution.

1.42. **Advertisement and promotion** - any notification or announcement that is made in printed, visual, electronic, radio media or any other method, in order to allow the implantation of tissues and cells.

1.43. **Serious adverse reaction** - the sudden and unintentional reaction on the donor or recipient, related to the expertise, removal, treatment, processing, preservation, transport and implantation of tissues and cells, which condition leads to death, life threatening conditions, spread of contagious diseases, permanent disability for work or diseases caused due to a prolonged stay in the healthcare institution.

1.44. **Serious adverse incident** -any harmful negative event related to the expertise, removal, treatment, processing, preservation, transport and implantation and tissues and cells, which condition can lead to death, life threatening conditions, spread of contagious diseases, permanent disability to work or diseases caused due to a prolonged stay in the healthcare institution.

1.45. **Investigation** - the set of actions applied to identify the tissue and the cell during each step, starting from selection, processing, testing, and preservation up to the distribution to the recipient or their disposal.

2. For purposes of this Law, nouns of masculine gender also imply nouns of feminine gender and vice versa without discrimination.

Article 4

Basic Principles

1. Removal of tissues and cells for the purpose of transplantation shall be made solely for the therapeutic benefit of the recipient.
2. The transplantation of tissues and cells shall be made only after the recipient and the donor have given their consent.
3. The transplantation shall be made under conditions that guarantee equal rights for the patients who need the transplantation and protection of human rights and freedoms, both for the donor and for the recipient.
4. The donation of tissues and cells is based on voluntary and unpaid donations, maintaining the anonymity, both of the donor and of the recipient, including their families, altruism of the donor and the solidarity between the donor and the recipient, respecting the life and health of the donor.

Article 5

1. Notwithstanding paragraph 4. of Article 4 of this Law, the donor may receive the compensation, which is limited to:
 - 1.1. medical expenses related to possible consequences to the donor caused by medical procedures before, during and after the transplantation procedure;
 - 1.2. material expenses related to the transport of the donor to the place of donation and performed analysis;
 - 1.3. essential and necessary medical examinations once a year, for the donor.
2. Conditions and criteria from paragraph 1. of this Article shall be determined by means of a sub-legal act by the Ministry of Health.

Article 6

1. The transplantation shall be performed in compliance with medical standards and the criteria that shall be determined with sub-legal act by the Ministry of Health.
2. The transplantation shall be performed only when other methods of therapy are less effective or are inapplicable.
3. The transplantation shall be performed only after completion of necessary medical tests in compliance with the medical transplantation standards, which shall guarantee maximal safety for the health of the donor and the recipient.

4. Medical specialists of respective field shall be obliged to provide conditions for reducing the risk of transfer of infections and other diseases from the donor to the recipient.

5. Medical specialists of respective field shall be obliged to provide qualitative conditions and security for tissues and cells for the performance of transplantation, regarding the activities dealing with the expertise, removal, processing preservation and implementation.

6. The conditions and criteria for professional qualification of the persons who perform the expertise, removal, treatment, processing, labeling, testing, procurement and preservation of tissues and cells shall be determined with sub-legal act by the Ministry of Health.

7. The persons from paragraph 6. of this Article shall undergo the mandatory training, at least once in two (2) years, according to the conditions as envisaged with sub-legal act as noted in the previous paragraph.

Article 7

1. It is prohibited the trading of human tissues and cells.

2. It is prohibited to sell-purchase transplants, and any kind of activity which favors the advertisement, trading and trafficking of transplants.

3. It is prohibited the distribution and publishing of data and information what enable the identification of the donor and the recipient.

4. It is prohibited the advertising and promotion of tissues and cells available for the purpose of financial gain and which are not in accordance with the adequate guidance.

5. It is prohibited the genetic manipulation of the embryo, even if performed for transplantation purposes.

6. It is prohibited to donate tissues and cells by alive underage donors, except under conditions as envisaged by this Law.

Article 8

Tissues and cells that cannot be used for transplantation for medical purposes may be allowed to be used for therapeutic, diagnostic, scientific-medical purposes according to sub-legal act as determined by the Ministry of Health.

CHAPTER II NATIONAL TRANSPLANTATION SYSTEM

Article 9

The National Transplantation System includes all state authorities and health institutions that perform activities related to the organizing, managing and controlling of the transplantation process.

Article 10

The Minister of Health shall allow the import and export of tissues and cells for transplantation purposes.

Article 11

1. For the purpose of organizing, coordinating, managing and controlling of the transplantation process there shall be established the Center of Transplants (hereinafter: the Center) and that is responsible for implementation of this Law.
2. The organizational structure of the Center shall be approved by the Government of Kosovo at the proposal of the Ministry.

Article 12 Transplant Coordination Center

1. The center consists of at least five (5) responsible officers who shall report to the manager.
2. The Officers of the Center shall be appointed based on the legislation in power.

Article 13 Manager of the Center

1. The Center shall be managed by the National Transplantations Manager.
2. As a Manager, there shall be appointed an indicated expert in the field of transplantations or in the field related to the transplantation process.
3. The Manager reports to the Minister regarding his work.

Article 14
Duties of the Center for Coordination of Transplantations

1. Center for Coordination of Transplantations carries out the following duties:
 - 1.1. controls and coordinates activities in the field of transplantation conducted in licensed health care institutions;
 - 1.2. proposes to the Minister medical standards for the transplantation of tissues and cells and medical criteria for the selection of the donor and recipient;
 - 1.3. creates and maintains the registries, collects, stores and enables access to information related to transplantations;
 4. ensures continuous and direct access of the authorized medical personnel to medical services of the potential donor or recipient, in the official registry of persons who have given their consent or objections to take their tissues and cells after their death;
 - 1.5. organizes the import and export of tissues and cells and controls the distribution of tissues and cells;
 - 1.6. registers preserves and analyses the information related to the details of the donor, the health condition of the donor, serious adverse incident and reaction related to the transplantation;
 - 1.7. studies, analysis and reports on medical, legal, ethical, religious, economical and social consequences resulting from the transplantation;
 - 1.8. notifies parties regarding the transplantation process in order to guarantee the equal transparency and access for all persons in need;
 - 1.9. cooperates with all state authorities, health and scientific institutions and organization and non-governmental organizations in the field of transplantation;
 - 1.10. takes part in drafting the national strategies, programs and international projects related to the transplantation process;
 - 1.11. controls the activities that the cells and tissues intended for implantation be safe and qualitative;
 - 1.12. organizes activities related to the stimulation of voluntary and free of charge donations of tissues and cells;
 - 1.13. defines parameters in order to ensure quality and safety of expertise, treatment, removal, processing, labeling, preservation, implantation, control and inspection of tissues and cells.

Article 15
The Bank of Tissues and Cells

1. The Bank is a health institution or unit of health institutions where specialists of relevant fields remove, study, preserve and process tissues and cells for medical purposes.
2. Banks perform the following activities:
 - 2.1. selection, assessment, testing of tissues and cells;
 - 2.2. their examination and processing;
 - 2.3. conservation, preservation, labeling and packaging of tissues and cells as well as to document their data;
 - 2.4. distribution of tissues, cells intended for transplantation.
3. The conditions, procedures, duties of banks for tissues and cells shall be determined with sub-legal act by the Ministry of Health.
4. In order to study, preserve, select, examine, conserve, distribute and process tissues and cells for medical purposes, the Minister, by means of a decision establishes the bank for tissues and cells.

Article 16
Ethical Transplantation Committee

1. The Ethical Transplantation Committee is established within the Ministry.
2. The Committee is appointed by the Ministry for a term of three years and consists of seven members who are indicated personalities in the field of medicine, biology, psychology, justice and other relevant fields in conjunction with transplantation.
3. The persons who take part in the transplantation process cannot be members of the Ethical Committee.
4. The Ethical Committee shall give its opinion regarding ethical and deontological matters in the field of transplantations and shall allow or prohibit the removal of tissues and cells from persons in cases when it is envisaged by law.
5. The meetings of the Ethical Committee shall be held behind closed doors.
6. The members of the Committee keep the reliability of all the data taken related to the realization of their activity, except for the cases when the data are made known at the consent of the donor, recipient or a legal representative.

7. The Ethical Committee approves or rejects the request of the health institution, regarding the realization of the removal of tissues and cells for the benefit of the recipient, who is not related to the donor by blood.
8. Proposes the main principles of the professional ethics for health professionals dealing with activities related to transplantations.
9. Monitors the implementation of the principles of professional ethics of health professionals for transplantation procedures in the territory of the Republic of Kosovo.
10. Coordinates the work of ethical commission for transplantation in health institutions.
11. Decides and gives its opinion on disputed matters of importance for transplantation in health institutions.
12. Monitors the implementation of decisions and reviews professional questions dealing with transplantation matters in health institutions and notifies the Ethical Board of the Chambers about this.
13. Prepares annual reports for the Ministry and reviews also other matters of professional ethics for the implementation of transplantations.
14. Activities of the Ethical Committee shall be financed by the Ministry of Health.
15. The conditions and work organization of the Ethical Committee shall be determined with sub-legal act by the Ministry of Health.

Article 17

External Experts of the Center

1. For professional matters within the scope of the Center, the manager has the right to engage external experts at the consent of the Minister.
2. External experts may be indicated professionals both within and outside of the field they are appointed for.
3. Experts are appointed according to the needs for a fixed term and for their work they shall be paid according to the legislation in power.

Article 18

Health Institutions for Transplantation of Tissues and Cells

1. The removal and implantation of tissues and cells shall be made in public, private and public-private health institutions.

2. Public health institutions are established, private health institutions are licensed, whereas public-private health institutions are created based on the legislation in power.
3. The activity from field of transplantation of tissues and cells may be conducted in health institutions of the Kosovo Security Force.
4. Health institutions from paragraph 2. and 3. of this Article shall register the origin and destination of tissues and cells intended for human application and all activities related to the expertise, removal, implantation, treatment, testing, processing, preservation, distribution and labeling that shall be performed in such institutions according to the conditions and procedures as envisaged with sub-legal act by the Ministry of Health.
5. Health institutions shall submit an annual report to the Center, on the performed activities according to paragraph 4. of this Article and this report must have public access.
6. The data from the report, based on paragraph 4. of this Article, shall be entered in the registry according to sub-paragraph 1.1. Article 45 of this Law and such report shall have access to official documents according to legal provisions in power.
7. The transport of tissues and cells for transplantation shall be performed by health institutions from paragraph 2. and 3. of this Article, and also from tissue and cell banks.
8. Health institutions shall ensure that all the tissues and cells be labeled with the identification code, in compliance with the quality assurance conditions.
9. Health institutions shall apply the identification system of the donor which includes the unique identification code for each donation and for each product related thereto.
10. Tissues and cells shall be kept in quarantine until the information and conditions related to the testing of the donor be completed in compliance with the provisions determining the criteria for the selection of tissues and cells of the donor, laboratory tests required for the donors and the tissue and cell supply procedure by the health institutions.
11. Until the establishment of the laboratory, the Minister shall authorize the responsible health institution for immune-genetic analysis with the purpose of specifying and testing the compatibility of tissues and cells of the donor with the recipient.

Article 19

1. Activities related to the expertise, removal, processing, re-processing, preservation and transport of tissues and cells for the needs of the transplantation process, shall be performed by health institutions according to paragraph 2. and 3. Article 18 of this Law and by tissue and cell banks.

2. Conditions and procedures related to the expertise, labeling, treatment, processing, preservation, distribution, quality assurance and safety, for the issuance of the license for health institutions for tissues and cells shall be determined by Ministry of Health with sub-legal act.

3. Conditions for accreditation of health institutions from paragraph 2. and 3. Article 18 of this Law shall be determined by Ministry of Health with sub-legal act.

Article 20

1. Health institutions by means of a written contract entered between them, shall be allowed to perform joint activities related to the removal, treatment, processing, preservation and/or implantation of tissues and cells.

2. Health institutions may enter a contract in writing with third parties in order to provide goods and services, which may have an impact on the quality and safety of tissues and cells.

3. Health institutions shall keep and maintain the registries related to the contracts entered into according to paragraph 1. and 2. of this Article.

4. Health institutions shall submit the copies of contracts concluded according to paragraph 1. and 2. of this Article to the Center, within seven (7) days from the day of contracting and shall maintain the list of written contracts entered into with third parties.

5. The contracts between the health institutions and third parties shall be in compliance with the tissue and cells processing process and shall specify in details the procedure and responsibilities of third parties.

6. At the request of competent authorities, health institutions shall give the copies of contract entered into with third parties.

7. Health institutions shall perform the implementation only for the persons registered in the registry of persons waiting for transplantation of tissues and cells.

8. Health institutions shall document in writing the use of the removed tissue and cells, in the protocol, which shall be enclosed to other associating documents for the removed transplant. This protocol shall contain in particular the date and location of removal, as well as the final purpose of the removed transplants.

9. In case a decision is taken that the removed tissues and cells are inappropriate, the reason of incompatibility as well as the manner of further treatment shall be written in the protocol.

10. Health institutions shall keep the data for the realized removals and implantations and write down the data for the removed tissues and cells in the protocol.

11. They shall submit the copy of the protocol to the Center within seven (7) days from the day of decision-taking for the final purpose of the transplants.

12. Health institutions shall ensure the quality of tissues and cells during the distribution.

13. In standard operational procedures, there shall be determined that the tissues and cells be disposed when necessary by the personnel, in order that other tissues and cells and the working environment be saved from contamination.

Article 21

1. Health institutions shall notify the Center within seven (7) days from the ascertainment of all serious adverse reactions and incidents, in case they result from the obtaining, implantation, storage, expertise, treatment, processing, preservation and distribution of tissues and cells intended for transplantation.

2. Health institutions are obliged to create and implement the system for immediate blockage, withdrawal or disposal of all tissues and cells which may lead to a serious adverse reaction or incident.

3. Conditions and procedures for the notification, registration, reporting and issuance of information for serious adverse reactions, their blockage, the removal and disposal of tissues and cells shall be determined with sub-legal act by the Minister.

4. Health institutions shall classify the tissues and cells that are taken for transplantation.

5. Health institutions are obliged to create conditions for the transfer of tissues and cells from the donor to the recipient and of materials and products having contact with them, which may have an impact to their safety and quality.

6. Conditions and procedures related to paragraph 5. of this Article shall be determined with sub-legal act issued by the Ministry of Health.

Article 22

1. All health institutions that conduct activities related to transplantation are obliged to appoint one person, who shall organize, control and be held responsible for the expertise, removal, treatment, processing, testing, classification, labeling, preservation, distribution and implantation of tissues and cells.

2. The person from paragraph 1. of this Article shall be obliged to notify if such a serious adverse reaction or incident occurs.

3. The person from paragraph 1. of this Article shall meet the following conditions:

3.1. be a specialist doctor related to the field of transplantation of tissues and cells or the field of biology;

3.2. have five (5) years of work experience in the relevant field;

3.3. the health institutions shall be obliged to notify the Center about the level of education and experience of the person from paragraph 1. of this Article within seven (7) days.

3.4. the health institution shall notify the Center in case the person from paragraph 1. of this Article is replaced by another responsible person including also the date when he started his duty.

3.5. obligations and responsibilities of the person from paragraph 1. of this Article shall be determined with sub-legal act issued by the Minister.

CHAPTER III REMOVAL OF TISSUES AND CELLS

Article 23

Removal of tissues and cells from the human corpse

1. Removal of tissues and cells from the human corpse for the purpose of transplantation is made after the confirmation of death pursuant to medical criteria according to the sub-legal act issued by the Ministry of Health.

2. Death shall be ascertained by the commission consisting of three (3) specialist doctors who shall be appointed by the Health Institutions.

3. Specialist doctors from paragraph 2. of this Article shall not take part in the teams which conduct the transplantation of tissues and cells.

4. It is not allowed the removal of tissues and cells for transplantation from the person who has not given his consent in writing during his life.

5. It is not allowed the removal of tissues and cells for transplantation from the corpse of the person who is under eighteen (18) years of age, except when there is given the consent in writing by his parent or custodian.

6. It is not allowed the removal of tissues and cells for transplantation from the human corpse of unknown identity.

7. If the human corpse is subject of forensic expertise, the removal of tissues and cells from the body shall be conducted by the forensic expert in conformity with legal provisions in power.

Article 24

1. The removal of tissues and cells from a dead person can be performed if one of the following conditions are met:

1.1. if there is registered consent in the official registry of the Center according to paragraph 1., sub-paragraph 1.5. Article 45 of this Law for the removal of tissues and cells after his death;

1.2. the removal of tissues and cells shall be allowed if there is a written consent filed within the reasonable short time, by:

1.2.1. spouse, parent or guardian;

1.2.2. adult child;

1.2.3. adult sibling.

2. The manner, procedure of ascertainment and verification of circumstances from paragraph 1. of this Article shall be determined with sub-legal act by the Minister.

Article 25

After the removal of tissues and cells, all necessary measures for the restoration of the appearance of the dead person shall be undertaken.

Article 26

Every health institution in which tissues and cells were taken from the human corpse shall be obliged to register the procedure in the Center within seven (7) days.

Article 27

Removal of tissues and cells from the alive donor

1. The removal of tissues and cells from the donor shall be made only under conditions which do not present any risk to him and in compliance with the written statement taken from him, having explained to him in an understandable language to the possible consequences.

2. The consent or objection for the removal of tissues and cells shall be verified by the Notary.
3. The familiarization of the donor with his rights, medical procedures and safety measures as determined by this law shall be made by a doctor who shall not take part in the transplantation.
4. The donor may withdraw his consent at any time before the removal of tissues and cells.
5. The removal of tissues and cells from the person who is under the age of eighteen (18), shall be allowed only in cases envisaged by this Law.
6. The removal of tissues and cells for transplantation from a person who does not possess the capacity to act shall not be allowed.
7. The physical and psychic health of the donor shall be determined by a commission appointed by the director of the health institution, which performs the removal of tissues and cells, consisting of at least three (3) specialist doctors who shall not take part in the medical team which shall take or implant the tissues and cells.
8. The Commission from paragraph 7. of this Article shall be obliged to issue an official report on the physical and psychic health of the donor.
9. It is prohibited to offer and give material profit to the donor of tissues and cells.

Article 28

1. Every citizen of the Republic of Kosovo or foreign citizen with permanent residence in the Republic of Kosovo has the right to express his will, during his life, regarding his consent or objections in writing regarding taking of the tissues and cells after his death.
2. The consent or objection expressed according to paragraph 1. of this Article can be given for all tissues and cells, or there may be specified for certain purposes, such as therapeutic, diagnostic, scientific or educational purposes.
3. The consent or objection for the removal of tissues and cells is given in writing by signing of the declaration before the specialist of family medicine.
4. The specialist of family medicine is obliged to register the consent or objection declared and notarized in the relevant health document and submit it to the Center within a term of seven (7) days.
5. A copy of the consent or objection shall remain the Main Center of Family Medicine, whereas one copy shall be given to the party which gives its consent or objection.

6. The health document from paragraph 4. of this Article shall be created by the Ministry of Health.

7. The health document from paragraph 4. of this Article shall be submitted from the Center to the Health Insurance Fund which shall keep a registry for such purpose.

8. The persons who have no health insurance or who have not selected the family doctor, may express their consent or objection in writing, regarding the removal of tissues and cells after their death, by signing the declaration at the Center, which notifies the party for the obligation of notarizing the consent or objection.

9. The declaration from paragraph 8. of this Article shall be signed in two copies, ensuring that one copy is given to the person who has expressed the consent or objection and one shall remain in the Center.

10. The specialist of family medicine is obliged to notify the Center regarding the consent or objection for taking of tissues and cells, within seven (7) days from the day of the declaration.

11. The consent or objection expressed in writing, according to paragraph 1. and paragraph 9. of this Article in conjunction with paragraph 8. of this Article shall be registered in the official registry in the Center in terms of three (3) days after receiving the notification according to paragraph 10. of this Article.

12. If the person has not given any consent or objection in writing regarding the donation of tissues and cells while he was alive, then after his death this may be done by his family members or guardian.

Article 29

1. The donor may be only the person who is the spouse or a close relative of the recipient indefinitely for a direct line or for collateral line up to the fourth degree, including the family relation due to adoption, but not earlier than three (3) years from the adoption, in cases when the recipient is an adopting parent, which shall be verified by means of official documentations.

2. As an exclusion, with the permit from the Ethical Committee for transplantation it shall be determined that a donor may be the person who:

2.1. currently cohabitates with the recipient for a period longer than two (2) years, and this partnership is an undisputed evidence.

2.2. is the biological parent of the recipient and has not adopted the child according to the procedure as envisaged by Law.

3. Hematopoietic cells may be taken from any person who possesses capacity to act.

Article 30

1. The removal of regenerating tissues from persons under eighteen (18) shall be made only when the transplantation is performed for the parent, spouse, sibling, child and when there are met the following conditions:

- 1.1. there is no compatible donor who is older than eighteen (18);
- 1.2. when the transplantation is a treatment which saves lives;
- 1.3. the recipient is included in the official Center for the coordination of transplantations;
- 1.4. the ethical committee for transplantations has given its permit.

2. In cases from paragraph 1. of this Article, there shall be requested the consent of the parents or the custodian of the donor.

Article 31

The taking of amniotic tissues and mother cells from the placenta, shall be made only after receiving the consent in writing from the pregnant woman.

Article 32

1. Each health institutions which performs the removal of tissues and cells from an alive donor is obliged to notify the Center at least seven (7) days in advance.
2. The health institutions, within a term of seven (7) days from the day of removal of tissues and cells from the donor is obliged to register the procedure in the Center.

Article 33

The removal of tissues and cells from animals

The conditions to use the tissues and cells of animal original shall be defined with sub-legal act by the Minister.

CHAPTER IV IMPLANTATION OF TISSUES AND CELLS

Article 34

1. Implantation of tissues and cells can be made only under the following conditions:
 - 1.1. the recipient or his legal representative has given his free will in writing for the oncoming implantation procedure;
 - 1.2. the donor is registered in the official registry of the Center.

Article 35

Non-realization of the removal of transplant

1. The removal of transplant from the donor shall not be realized if:
 - 1.1. it is judged that the transplant may seriously harm the health or life of the donor;
 - 1.2. the donor is a person in detention or serving a punishment in prison. Cases of donations between parents and their children, between siblings and between spouses are an exception;
 - 1.3. during the assessment of the health condition of the donor, it is suspected that the donor suffers from a disease or condition, which may endanger the health or life of the recipient. This shall not be applied for the cases when the risk towards the donor is small compared to the transplant which saves a life.

Article 36

The inclusion of persons in the official registry who need transplantation and the selection of the concrete recipient of tissues and cells shall be made according to the conditions determined with sub-legal act by the Ministry of Health.

Article 37

Health institutions according to paragraph 2. and 3. Article 18 of this Law shall perform the medical activities regarding the selection and preparation of the potential recipient, continuous supervision, control of the health condition and post-operative treatment of the patient.

Article 38

Every health institution which has performed the implantation of tissues or cells is obliged to register the transplantation in the Center within seven (7) days.

CHAPTER V SAFETY AND QUALITY

Article 39 Quality management

1. The Ministry of Health undertakes all the measures to assure that health institutions that deal with transplantation must implement and update a quality assurance system, based on the principles of good practice.
2. Quality assurance of the transplant includes the standards, rules dealing with:
 - 2.1. the documentation system including the standard procedures of operation, instruction and manuals for training, reporting forms , details for the donor and information on the final destination of tissues and cells.
 - 2.2. environment and equipment;
 - 2.3. personnel;
 - 2.4. the selection procedure of donors of tissues and cells;
 - 2.5. the acceptance procedure of tissues and cells in health institutions;
 - 2.6. the procedure for testing, processing and supply of tissues and cells;
 - 2.7. the procedure for labeling, preservation, documentation, packaging, depositing and distribution of tissues and cells;
 - 2.8. the criteria and procedure for the direct distribution of specific tissues and cells to the recipient;
 - 2.9. the procedure for the treatment of tissues and cells that shall be disposed, in order to prevent the contamination of other tissues and cells, personnel and the environment.
3. Health institutions performing transplantations undertake all the necessary measure to guarantee that the quality system includes at least the following documentation:

- 3.1. the standard operative procedure for each procedure that is undertaken;
 - 3.2. guidelines;
 - 3.3. the training and referring manual;
 - 3.4. the reporting form;
 - 3.5. details of the donor;
 - 3.6. data for the final distribution of tissues and cells.
4. Health institutions are obliged to ensure that such documentation is available for inspection by competent authorities.
 5. Health institutions that deal with transplantation must maintain all the necessary data in order to guarantee investigation.
 6. Rules for the evaluation of quality and safety of tissues and cells for transplantation purposes shall be determined with sub-legal act issued by the Ministry of Health

Article 40 **Reporting adverse effects**

1. Health institutions performing transplantations are obliged to report to the bank for tissues and cells, whenever an adverse reaction or incident appears.
2. The procedure for the reporting of effects from paragraph 1. of this Article as well as for the processing of data for such cases shall be determined with sub-legal act issued by the Ministry of Health.

Article 41 **Import and export of tissues and cells**

1. The bank of tissues and cells is the institution which imports and exports transplants, based on the procedures envisaged with sub-legal act issued by the Ministry of Health.
2. The list of requirements, which shall be met to export and import tissues and cells in and from other countries, must include the investigation conditions and manners, registration of the investigated data, verification of the administration of transplants, the adverse effects reporting system as well as the procedure for the verification of equal standards of quality and safety. The Procedure for export and import of tissues and cells shall be determined with sub-legal act issued by the Ministry of Health.

3. The center shall ensure that the tissues and cells that are imported and exported meet the quality and safety standards in compliance with the conditions required by this law and international standards.
4. In emergency cases, the import and export of tissues and cells may be authorized directly by the Minister.
5. The import and export of specific tissues and cells may be authorized directly by the Minister.
6. The export of tissues and cells shall be made upon meeting the needs in the country, at the proposal of the Manager of the Center and with permission of the Minister of Health, according to the conditions determined with sub-legal act.
7. The import of tissues and cells shall be made when the need for tissues and cells cannot be fulfilled in the country, at the proposal of the Manager of the Center and with permission of the Minister of Health, according to the conditions determined with sub-legal act

Article 42 Investigation

1. The establishment and functioning of the investigation system shall be determined with sub-legal act issued by the Ministry of Health and shall include:
 - 1.1. investigation from the donor towards the recipient and vice versa of tissues and cells selected, processed or distributed in the territory of the country. Investigation shall be applied also for all relevant data related to the products and materials which make come to contact with tissues and cells;
 - 1.2. implementation of a donor identification system, to which a special code for each donation and product related it shall be attached;
 - 1.3. registration and preservation of data necessary to guarantee investigation in all stages.
2. The data requested for the complete investigation shall be stored for at least thirty (30) years after clinical use. The data, shall also be saved electronically.

Article 43 Inspection

1. The Ministry organizes the inspection and undertakes the relevant law enforcement measures.

2. The Ministry shall organize inspections anytime a serious adverse reaction or incident occurs.
3. The inspections according to the circumstances from paragraph 2. of this Article shall be performed also at the request of the competent authorities of other countries.
4. At the request of competent authorities of other countries, the Ministry shall provide information on the result of inspections and the measures of control performed regarding the fulfillment of conditions envisaged by this Law.
5. The Ministry shall suspend or revoke the license, accreditation of health institutions or the tissues and cell processing that shall be made in such institutions, if the inspection and the control measures prove that the health institutions or the process is not being performed in compliance with the conditions as envisaged by this Law.
6. If within a period of one year the transplantation results are not approximate to the results of relevant institutions of EU member states, the Minister shall revoke the license.
7. The conditions, procedures of inspections and control measures and the necessary training and qualification of inspectors shall be determined with sub-legal act by the Ministry of Health.
8. The health inspectorate has the following rights:
 - 8.1. to periodically inspect healthcare institutions performing activities related to the transplantation of tissues and cells and the equipment of any third party specified in the contract between the health institution and the third party;
 - 8.2. the time period between two inspections shall not exceed one (1) year;
 - 8.3. to evaluate and verify the procedures and activities performed in the health institutions where transplantations are being conducted;
 - 8.4. to control any document or other data related to the inspection object.

Article 44
Saving of data and information

1. All health institutions and authorities and other entities performing activities related to tissue and cell transplantation in accordance with the provisions of this law, shall be obliged to keep records and relevant information for a period of at least thirty (30) years.
2. Health institutions performing activities in the field of transplantation should ensure confidentiality of personal, medical and genetic data of the donor and recipient, in order not to identify the donor or recipient, based on the applicable law.

3. The data and documents from paragraph 2. of this Article represent classified health information and shall be stored in compliance with legal provisions for the protection of classified health information and personal data.
4. In order to keep the confidentiality, the relevant institutions shall take measures to protect the data system, and secure it them from any unauthorized addition, removal or modification of data in the donor's file or from moving and transferring data.
5. The personal data of the donor and recipient cannot be used for scientific purposes or published in the media.
6. The Ministry of Health may use such data and information only for the purpose of drafting health policies that shall have an impact on the health of citizens.
7. The data may be used for scientific, educational and statistical purposes only upon receiving a written permission of the donor and recipient.

CHAPTER VI REGISTRY AND CONTROL

Article 45

1. The center shall compile and maintain:
 - 1.1. the public registry;
 - 1.2. the registry of persons waiting for a transplant of tissues and cells;
 - 1.3. the registry of donors of transplants;
 - 1.4. the registry of conducted transplantations;
 - 1.5. the official registry enlisting the names of persons who have expressed their consent or objection for the removal of tissues and cells.
2. The registry from sub-paragraph 1.1. of this Article shall have public access for specific activities for accreditation, design, authorization or licensing of health institutions for transplantation of tissues and cells and shall not contain personal data.
3. The data of the official registry shall be saved for a period of thirty (30) years. Citizens shall have the right to verify if their consent or objection is registered in the official registry.

CHAPTER VII FINANCING

Article 46

1. The Ministry shall finance the following activities:
 - 1.1. designing and implementing the technology for establishing an information system for the registration and control of the transplantation process.
 - 1.2. educational and scientific improvement in the field of transplantation.
 - 1.3. health programs and projects of national importance in the field of transplantation;
 - 1.4. the Health Insurance Fund may finance the activities related to transplantations based on the written contracts entered into with health institutions;
 - 1.5. the contracts under sub-paragraph 1.4. of this Article shall be effective after their approval and registration in the registry by the Center.
2. Natural persons and legal entities may donate funds for activities related to transplantation based on the written contracts entered into with health care institutions.
3. For the contract under paragraph 2. of this Article, sub-paragraph 1.5. of this Article shall be applied where applicable.

CHAPTER VIII SANCTIONS

Article 47

Administrative sanctions

1. The offences listed below, when not constituting a crime, they constitute an administrative sanction punishable according to this chapter.
2. For the offences listed below, a natural person shall be punished as follows:
 - 2.1. a natural person who violates the provisions of Article 6 and 7 of this Law shall be imposed a fine of seven thousand (7.000,00) Euros, or withdrawal of the right to exercise the profession for three (3) years;

2.2. a natural person who violates the provisions of paragraph 2. Article 22 of this Law, shall be imposed a fine of five hundred (500.00) Euros, or withdrawal of the right to exercise the profession for one (1) year;

2.3. conducting of the transplantation procedure without complying to the procedures set forth under Article 23 and 24 of this Law shall be punished with withdrawal of the responsible person's right to exercise the profession for three (3) years;

2.4. conducting of the transplantation of tissues and cells without prior consent of the donor or recipient, as envisaged under Article 27 and 34 of this Law, shall be punished with withdrawal of the right to exercise the profession for three (3) years;

2.5. a natural person violating the provisions of paragraph 4. and 10. Article 28 of this Law shall be imposed a fine of five hundred (500.00) Euros;

2.6. the removal of the transplant from the donor, when his/her life is in danger, when detained or imprisoned, suffering from a disease that may endanger the life of the recipient as set forth in Article 35 of this Law, shall be punished with withdrawal of the right to exercise the profession for three (3) years;

2.7. conducting of the transplantation procedure by not complying with the procedures set forth in Article 27 of this Law shall be punished with withdrawal of the responsible person's right to exercise the profession for a period of five (5) years;

2.8. importing and exporting in violation of Article 41 of this Law shall be punished with withdrawal of the responsible person's right to exercise the profession for a period of five (5) years;

2.9. the violation of the provisions on the protection of data and information, as set forth in Article 44 of this Law shall be punished with withdrawal of the right to exercise the profession for three (3) years.

3. For violations listed below, a legal entity shall be punished as follows:

3.1. a legal entity violating the provisions of Article 6 and 7 of this Law shall be imposed a fine of twenty thousand (20.000,00) Euros;

3.2. a legal entity violating the provisions of , paragraphs 4., 5., 8., 9. and 10. Article 18 of this Law shall be imposed a fine of twenty thousand (20.000,00) Euro, and suspension of the license of the relevant health institutions for a period of one (1) year. In case of re-violation, the license of the relevant health institution shall be revoked;

- 3.3. a legal entity violating the provisions of Article 20 and 21 of this Law shall be imposed a fine of twenty thousand (20.000,00) Euros and with suspension of the license of the relevant health institution for a period of one (1) year. In case of re-violation, the license of the relevant health institution shall be revoked;
- 3.4. conducting of the transplantation procedure by not respecting the procedures set forth in Articles 23 and 24 of this Law, shall be punished with suspension of the license of the relevant health institution for a period of one (1) year. In case of re-violation, the license of the relevant health institution shall be revoked;
- 3.5. a legal entity violating the provisions of Articles 22, 25, 26 and 32 of this Law shall be imposed a fine of seven thousand (7.000,00) Euro;
- 3.6. a legal entity violating the provisions of Articles 27, 29, 30 and 31 of this Law shall be imposed a fine of fifteen thousand (15.000,00) Euros and with suspension of the license of the relevant health institution for a period of three (3) years. In case of re-violation, the license of the relevant health institution shall be revoked;
- 3.7. a legal entity violating the provisions of Articles 34 and 35 of this Law shall be sanctioned with suspension of the license of the relevant health institution for a period of one (1) year. In case of re-violation, the license of the relevant health institution shall be revoked;
- 3.8. failure to report adverse effects by the health institutions conducting transplantation in violation of Article 40 of this Law, shall be fined with ten thousand (10.000,00) Euros;
- 3.9. the import and export in violation of Article 41 of this Law shall be fined with twenty thousand (20.000,00) Euros;
- 3.10. the violation of the provisions for the protection of data and information, as set forth in Article 44 of this Law by health institutions shall be fined with ten thousand (10.000,00) Euros.
4. The authority responsible for imposing and executing the fine shall be the Ministry of Health. The authorities responsible for withdrawing the right to exercise the profession shall be the chambers of health professionals.

Article 48
Execution

1. An appeal filed against the decision of the inspectorate does not prolong the execution of the decision, unless otherwise envisaged by legal provisions regulating the activity of the health inspectorate.
2. The fine shall be paid to the relevant bank-account of the Ministry of Health and shall be transferred to the budget of Kosovo.
3. If the party does not pay the fine voluntarily, within due time, the health inspectorate shall notify the party about the application of enforcement measures for the execution of the decision.
4. The notification under paragraph 3. of this Article shall contain information informing the party that the fine will be replaced with imprisonment in case of failure to pay the fine within due time.
5. If the party does not pay the fine within due time as set forth in paragraph 3. of this Article, the health inspectorate shall submit the case to the competent court for execution with supporting documents enclosed.
6. At the request of the health inspectorate, the Kosovo Police shall be obliged to support the inspectorate.

Article 49
Criminal Offences

Violences that lead to a criminal offence, shall be punished according to the Provisions of Criminal Code of the Republic of Kosovo

CHAPTER X
FINAL PROVISIONS

Article 50
Issuing sub-legal acts

Ministry of Health, in terms of six (6) months, from the day of entrance into force of this Law, shall issue sub-legal acts foreseen by this Law.

Article 51
Entry into force

This law shall enter into force fifteen (15) days after its publication in the Official Gazette of the Republic of Kosovo.

Law No. 04/L-192
20 March 2014

President of the Assembly of the Republic of Kosovo

Jakup KRASNIQI