LAW No. 9 of 18 January 2016
for the ratification of the Additional Protocol to the European Convention for the Protection of Human Rights and Dignity of the Human Being with regard to Applications of Biology and Medicine, concerning the Transplantation of Organs and Tissues of Human Origin, signed in Strasbourg on 20 February 2015
Issuer: Parliament
Published in the OFFICIAL GAZZET No. 62 of 28 January 2016

The Romanian Parliament adopts this law.

Sole Article
The Additional Protocol to the European Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine to Transplantation of Organs and Tissues of Human Origin, signed in Strasbourg on 20 February 2015, is hereby ratified.

This law was adopted by the Romanian Parliament, in compliance with the provisions of Article 75 and Article 76 par. (2) of the Romanian Constitution, republished.

THE PRESIDENT OF THE CHAMBER OF DEPUTIES

VALERIU-ŞTEFAN ZGONEA

THE PRESIDENT OF THE SENATE

CĂLIN-CONSTANTIN-ANTON POPESCU-TĂRICEANU

Bucharest, 18 January 2016
n. 9

ADDITIONAL PROTOCOL of 20 February 2015
to the Convention on Human Rights and Biomedicine, concerning Transplantation of Organs and Tissues of Human Origin
Issuer: INTERNATIONAL ACT
Published in the OFFICIAL MONITOR No 62 of 28 January 2016

Preamble
The member States of the Council of Europe, the other States and the European Community, signatories to this Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (hereinafter referred to as the Convention on Human Rights and Biomedicine),
bearing in mind that the aim of the Council of Europe is to achieve a greater unity between its members and that one of the means of achieving this aim is the protection and development of human rights and fundamental freedoms,
having regard to the fact that the aim of the Convention on Human Rights and Biomedicine, as defined in Article 1 thereof, is to protect the dignity and identity of the human being and to guarantee everyone, without discrimination, respect for his integrity and other fundamental rights and freedoms with regard to the application of biology and medicine,
bearing in mind that progress in the medical sciences, in particular in the field of organ and tissue transplantation, contributes to saving human lives or significantly improving the quality of human life,
given that organ and tissue transplantation is an integral part of the health services offered to the population,
Given the shortage of organs and tissues, appropriate measures should be taken to increase donation, in particular by informing the public about the importance of organ and tissue transplantation and by promoting cooperation in Europe in this field,

taking also into account the ethical, psychological and socio-cultural issues inherent in organ and tissue transplantation,
bearing in mind that inappropriate use of organs or tissues could endanger human life, well-being or dignity,
bearing in mind that organ and tissue transplantation should be carried out under conditions that protect the rights and freedoms of donors, potential donors and recipients of organs and tissues, and that institutions must be instrumental in helping to ensure that these conditions are respected,
recognising that, in facilitating organ and tissue transplantation in Europe in the interest of patients, it is necessary to monitor respect for individual rights and freedoms and to prevent the commercialisation of human body parts in the procurement, exchange and allocation of organs and tissues,
taking into account the previous work of the Committee of Ministers and the Parliamentary Assembly of the Council of Europe in this field,
Determined to take appropriate measures in the field of organ and tissue transplantation in order to guarantee the dignity of the human being and fundamental human rights and freedoms,
have agreed as follows:

Note:
Strasbourg, 24.01.2002.
The Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community entered into force on 1 December 2009. Accordingly, from that date, any reference to the European Community should be read as the European Union.

Chapter I Subject matter and scope

Article 1
Subject matter
The Parties to this Protocol shall protect the dignity and identity of the human person and guarantee, without discrimination, respect for his or her integrity and other fundamental rights and freedoms with regard to the transplantation of organs and tissues of human origin.

Article 2
Scope and definitions
1. This Protocol shall apply to the transplantation of organs and tissues of human origin for therapeutic purposes.
2. The provisions of this Protocol applicable to tissues shall also apply to cells, including haematopoietic stem cells.
3. The Protocol shall not apply:
a. reproductive organs and tissues;
b. embryonic or foetal organs and tissues;
c. Blood and blood derivatives.
4. For the purposes of this Protocol:
- the term "transplant" means the entire procedure involving the removal of an organ or tissue from one person and the grafting of that organ or tissue to another person, including the entire process of preparation, preservation and storage;
- subject to the provisions of Article 20, the term 'retrieval' means removal for the purpose of implantation.

Chapter II General provisions

Article 3
Transplantation system

The Parties shall ensure that there is a system in place to provide equitable access for patients to transplantation services.

Subject to the provisions of Chapter III, organs and, where appropriate, tissues shall be allocated only to patients registered on an official waiting list, according to transparent, objective and duly justified rules in terms of medical criteria. Within this framework, the persons or bodies responsible for taking the allocation decision are designated.

With regard to international agreements on organ exchange, the procedures must also ensure an effective and justified distribution among all participating countries, taking into account the principle of solidarity within each country.

The transplantation system ensures the collection and recording of information necessary to ensure the traceability of organs and tissues.

Article 4
Professional obligations and rules of conduct

Any intervention in the field of organ or tissue transplantation shall be carried out in compliance with professional rules and obligations.

Article 5
Information to the recipient

The recipient and, where appropriate, the person or body responsible for authorising the implantation shall be adequately informed in advance of the purpose and nature of the implantation, its consequences and risks, as well as of the alternatives to the intervention.

Article 6
Health and safety

Professionals involved in organ or tissue transplantation shall take all reasonable steps to minimise the risks of transmitting a disease to the recipient and to avoid any action that might render the organ or tissue unsuitable for implantation.

Article 7
Medical follow-up

Appropriate medical follow-up of both the living donor and the recipient after transplantation is proposed.

Article 8
Information to health professionals and the public

The Parties shall inform health professionals and the general public of the need for organs and tissues. They shall also publish information on the conditions for organ and tissue removal and implantation, including on consent or authorisation regimes, in particular regarding removal from deceased persons.

Chapter III Organ and tissue removal from living persons

Article 9
General rule

The removal of organs or tissues may be carried out from a living donor only in the therapeutic interest of the recipient and provided that there are no suitable organs or tissues available from a deceased person and no alternative therapeutic method of comparable effectiveness.

Article 10
Potential organ donors
The removal of organs from a living donor may be carried out for the benefit of a recipient who has a close personal relationship with that donor, as defined by law, or, in the absence of such a relationship, only under the conditions defined by law and after authorisation by an appropriate independent body.

Article 11
Risk assessment for the donor
Prior to the removal of organs or tissues, appropriate investigations and medical interventions shall be carried out to assess and limit the risks to the physical or mental health of the donor.
Procurement may not be carried out if there is a significant risk to the life and health of the donor.

Article 12
Donor information
The donor and, where appropriate, the person or body responsible for authorisation pursuant to Article 14(2) of this Protocol shall be adequately informed in advance of the purpose and nature of the procurement and of its consequences and risks.
They shall also be informed of the legal rights and safeguards for the protection of the donor. In particular, they shall be informed of their right to receive independent information on the risks of the procurement from a health professional with appropriate experience and who is not involved in the removal of the organ or tissues concerned or in the subsequent stages of the transplantation.

Article 13
Consent of the living donor
Subject to Articles 14 and 15 of this Protocol, an organ or tissue may be removed from a living donor only after the person concerned has given his free, informed and specific consent, either in writing or before an official body.
The person concerned may freely withdraw consent at any time.

Article 14
Protection of persons who lack the capacity to consent to organ or tissue removal
1. Any removal of organs or tissues from a person who does not have the capacity to consent in accordance with Article 13 of this Protocol shall be prohibited.
2. Exceptionally and under the conditions of protection provided by law, the procurement of renewable tissues from a person who lacks the capacity to consent may be authorised if the following conditions are met:
(i) there is no compatible donor available who has the capacity to consent;
(ii) the recipient is the brother or sister of the donor;
(iii) the donation is likely to save the recipient's life;
(iv) the authorisation of the representative, an authority or a person or body prescribed by law has been specifically granted in writing in agreement with the competent body;
(v) the prospective donor does not refuse.

Article 15
Collection of cells from a living donor
The law may provide that the provisions of Article 14(2)(ii) and (iii) shall not apply to cells if it is established that their procurement involves minimal risk and minimal hardship to the donor.

Chapter IV Removal of organs and tissues from deceased persons

Article 16
Establishment of death

The removal of organs or tissues from a deceased person may be carried out only if death has been duly ascertained in accordance with the law.
Doctors who ascertain the death of a person must be different from those who are directly involved in the removal of organs or tissues from that person and from those responsible for the care of any recipients of those organs or tissues.

Article 17
Consent and authorisations
Organs or tissues may be removed from the body of a deceased person only with the consent or authorisation required by law.
The removal shall not be carried out if the deceased was against it.

Article 18
Respect for the human body
During removal, the human body shall be treated with respect and every reasonable step shall be taken to restore the appearance of the body.

Article 19
Promotion of donation
Parties shall take all appropriate measures to promote organ and tissue donation.

Chapter V Implantation of an organ or tissues removed for purposes other than donation for implantation

Article 20
Implantation of an organ or tissues procured for purposes other than donation for implantation
1. Where an organ or tissues are removed from a person for a purpose other than donation for implantation, the organ or tissues may be implanted only if the possible consequences and risks have been explained to that person and informed consent has been obtained or, in the case of a person who lacks the capacity to consent, the appropriate authorisation has been obtained.
2. All the provisions of this Protocol shall apply to the situations referred to in paragraph 1, except those contained in Chapters III and IV.
Chapter VI Prohibition of financial gain

Article 21
Prohibition of financial gain
1. The human body and its parts shall not, as such, be a source of financial gain or comparable advantages.
Payments which do not constitute financial gain or comparable advantage, in particular, are not covered by this provision:
- compensation for loss of income suffered by the living donor and for any justifiable expenses incurred in connection with the procurement or related medical examinations;
- payments of justified fees for the performance of medical acts and related technical services performed in connection with the transplantation;
- compensation in the event of unjustified damage resulting from the removal of organs or tissues from the living donor.
2. Advertising the need for or availability of organs for the purpose of offering or obtaining financial gain or comparable advantage shall be prohibited.

Article 22
Prohibition of trafficking in organs and tissues
Trafficking in organs and tissues shall be prohibited.

Chapter VII Confidentiality

Article 23

Confidentiality

1. All personal data relating to the person from whom the organ or tissue removal has been carried out, as well as data relating to the recipient, must be considered confidential. They may be collected, processed or communicated only in accordance with the rules on professional secrecy and the protection of personal data.
2. The provisions of the preceding paragraph shall be without prejudice to provisions allowing, subject to appropriate safeguards, the collection, processing and communication of the necessary information on the person from whom the removal was carried out or on the recipient(s) of organs or tissues, if required for medical reasons, including traceability, in accordance with Article 3 of this Protocol.

Chapter VIII Violation of the provisions of the Protocol

Article 24
Violation of rights or principles

The Parties shall provide adequate judicial protection with a view to preventing or bringing about the cessation within a short period of time of an unlawful violation of the rights and principles recognised in this Protocol.

Article 25
Compensation for unjustified damage

A person who has suffered unjustified harm resulting from a transplantation shall be entitled to fair compensation under the conditions and in the manner prescribed by law.

Article 26
Penalties

The Parties shall provide for appropriate penalties in case of violation of the provisions of this Protocol.

Chapter IX Cooperation between Parties

Article 27
Cooperation between the Parties

The Parties shall take appropriate measures to ensure effective cooperation between them in the field of organ and tissue transplantation, including through the exchange of information.
In particular, they shall take appropriate measures to facilitate the rapid and safe transport of organs and tissues from or to their territories.

Chapter X Relationship between this Protocol and the Convention and review of the Protocol

Article 28
Relationship between this Protocol and the Convention

The Parties shall consider Articles 1 to 27 of this Protocol as additional acts to the Convention on Human Rights and Biomedicine and all provisions of the Convention shall apply accordingly.

Article 29
Review of the Protocol

In order to take account of scientific developments, this Protocol shall be reviewed by the Committee referred to in Article 32 of the Convention on Human Rights and Biomedicine not later than five years after the entry into force of the Protocol and thereafter at intervals to be determined by the Committee.

Chapter XI Final Clauses

Article 30
Signature and ratification
This Protocol shall be open for signature by the signatories to the Convention. It shall be subject to ratification, acceptance or approval. A Signatory may not ratify, accept or approve this Protocol without having previously ratified, accepted or approved the Convention. Instruments of ratification, acceptance or approval shall be deposited with the Secretary General of the Council of Europe.

Article 31
Entry into force
1. This Protocol shall enter into force on the first day of the month following the expiration of a period of three months after the date on which five States, including at least four member States of the Council of Europe, have expressed their consent to be bound by the Protocol in accordance with the provisions of Article 30.
2. In respect of any Signatory which subsequently expresses its consent to be bound by the Protocol, the Protocol shall enter into force on the first day of the month following the expiration of a period of three months after the date of deposit of its instrument of ratification, acceptance or approval.

Article 32
Accession
1. After the entry into force of this Protocol, any State which has acceded to the Convention may also accede to this Protocol.
2. Accession shall be effected by the deposit with the Secretary General of the Council of Europe of an instrument of accession which shall enter into force on the first day of the month following the expiration of a period of three months after the date of its deposit.

Article 33
Denunciation
1. Any Party may denounce this Protocol at any time by notifying the Secretary General of the Council of Europe.
2. Denunciation shall enter into force on the first day of the month following the expiration of a period of three months after the date of receipt of the notification by the Secretary General.

Article 34
Notification
The Secretary General of the Council of Europe shall notify all member States of the Council of Europe, the European Community, any Signatory, any Party and any other State which has been invited to accede to the Convention of:
(a) any signature;
b) the deposit of any instrument of ratification, acceptance, approval or accession;
c) any date of entry into force of this Protocol in accordance with Articles 31 and 32;
d) any other act, notification or communication relating to this Protocol.
In witness whereof we, the undersigned, being duly authorised thereto, have signed this Protocol.
Done at Strasbourg, this 24th day of January 2002, in the English and French languages, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to the non-member States which have participated in the elaboration of this Protocol, to any State invited to accede to the Convention and to the European Community.

Title VI The removal and transplantation of organs, tissues and cells of human origin for therapeutic purposes

Chapter I General provisions
Article 141

(1) Donation and transplantation of organs, tissues and cells of human origin shall be carried out for therapeutic purposes, ensuring standards of quality and safety in order to guarantee a high level of protection of human health, under the conditions laid down in this Title.
(2) This Act shall apply to the donation, testing, evaluation, procurement, preservation, distribution, transport and transplantation of organs, tissues and cells of human origin intended for transplantation.
(3) Where such organs, tissues and cells of human origin are used for research purposes, this Act shall not apply unless they are intended for human transplantation.

Article 142

For the purposes of this Title, the following terms and expressions shall have the following meaning:
a) accreditation - the granting by the National Transplant Agency of the right to carry out activities of donation, procurement, preservation and transplantation of organs, tissues and cells of human origin according to the specifics of each activity, after ascertaining the fulfilment of the criteria established by order of the Minister of Health. Accreditation is carried out by the National Transplant Agency;
(as of 30-09-2015, Letter a) of Article 142 was amended by CORRIGENDUM No 95 of 14 April 2006, published in the OFFICIAL MONITOR No 732 of 30 September 2015.)
b) competent authority - institutions responsible for coordination, supervision, accreditation and inspection of transplantation activity, as well as implementation of any provisions concerning transplantation activity;
c) authorisation - a document issued by the National Transplant Agency to allow the introduction or removal of organs, tissues and/or cells of human origin into or from the country, under the conditions that donation, procurement, processing, preservation, storage and transplantation are carried out in establishments accredited and/or approved by the National Transplant Agency;
(as of 30-09-2015, Letter c) of Article 142 was amended by CORRIGENDUM No 95 of 14 April 2006, published in the OFFICIAL MONITOR No 732 of 30 September 2015.)
d) special authorisation - document issued by the National Transplant Agency to allow the introduction or removal of placental blood, cord blood and tissues of human origin into/out of the country for a maximum period of one year, under the conditions that the processing, preservation and storage are done in a bank accredited/approved by the National Transplant Agency;
(as of 30-09-2015, Letter d) of Article 142 was amended by CORRIGENDUM No 95 of 14 April 2006, published in the OFFICIAL MONITOR No 732 of 30 September 2015.)
e) approved bank - bank of tissues and cells of human origin located outside the territory of Romania. For third countries the bank must comply with the quality and safety standards required by Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells and provide supporting documentation to this effect. For European Union Member States, the bank must be accredited by the competent authority of that country;
f) Tissue and cell bank - an accredited/accredited health care establishment engaged in the processing, preservation, storage or distribution of human tissues and cells;
g) Cell - the elementary anatomical and functional unit of living matter. For the purposes of this Act, the term cell/cells refers to the individual human cell or a collection of human cells, which are not joined by any form of intercellular substance;
h) procurement centre - a public or private health facility, medical team or department within a hospital, person or any other body that performs and/or coordinates organ, tissue and/or cell procurement and is accredited in the field of transplantation;
(i) transplant centre - a public or private health establishment, a medical team or a department within a hospital or any other body that performs transplantation of organs, tissues and cells of human origin and is accredited in the field of transplantation;
j) Preservation - the use of chemical agents, changes in environmental conditions or other means to prevent or delay biological or physical deterioration of organs, tissues and cells from procurement to transplantation;
k) destruction - the final destination of an organ, tissue or cell if it is not used for transplantation;
l) donation - the act of giving organs, tissues and/or cells intended for transplantation;
m) donor - a person who donates one or more organs, tissues and/or cells of human origin for therapeutic use, regardless of whether the donation took place during the lifetime of the person concerned or after his/her death;

n) donor assessment - the collection of relevant information on the characteristics of the donor necessary to assess the donor's eligibility to donate organs, tissues and cells in order to make an appropriate risk assessment with a view to minimising risks to the recipient and to optimising the allocation of organs, tissues and cells;
(o) organ evaluation - the collection of relevant information on the characteristics of the organ necessary to assess its suitability, to make an appropriate assessment of the risks in order to minimise them for the recipient and to optimise organ allocation;
p) Severe adverse event - any undesirable and unexpected event occurring at any stage of the chain from donation to transplantation that could result in the transmission of a communicable disease, death or life-threatening, disabling or incapacitating conditions for the patient or which could result in or prolong hospitalisation or morbidity;
q) Organ - a differentiated part of the structure of an organism, adapted to a defined function, consisting of several tissues or cell types, with their own vascularisation and innervation. A part of an organ is also an organ in the sense indicated if it is intended for use in the human body for the same purpose as the whole organ, while maintaining the requirements of structure and vascularisation;
r) European organ exchange organisation - a not-for-profit organisation, public or private, dedicated to the national and cross-border exchange of organs, the majority of whose member countries are Member States of the European Union;
s) retrieval - the collection of organs and/or tissues and/or cells of human origin that are morphologically and functionally healthy for the purpose of transplantation procedures;
(ș) recipient - a person who receives an organ and/or tissue and/or cell transplant;
*
This point transposes the provisions of Article 3(m) of 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, published in the Official Journal of the European Union, L 207 of 6 August 2010.
t) Operational procedures - written instructions describing the steps in a specific process, including the materials and methods to be used and the expected end result;
ț) Severe adverse reaction - an undesirable reaction, including a transmissible disease, in the living donor or in the recipient, occurring at any stage of the chain from donation to transplantation, which is fatal, life-threatening or results in disability or incapacity of the patient or which causes or prolongs hospitalisation or morbidity;
(u) transplantation - that medical activity whereby, for therapeutic purposes, an organ, tissue or cell removed from/by another person, called the donor, is implanted or grafted into the body of a patient, hereinafter referred to as the recipient. The regulations contained in this Act also apply to in vitro fertilisation techniques;
(v) traceability - the ability to locate and identify the organ, tissue or cell at any stage of the chain from donation to transplantation or destruction, including the ability to identify the donor and the procurement establishment, the recipient and the transplantation establishment, to locate and identify all relevant non-personal information on products and materials that come into contact with the organ, tissue or cell;
w) tissue - a grouping of differentiated cells, united by amorphous intercellular substance, which together form a topographical and functional association;
x) accredited health care establishment - a public or private health care establishment that fulfils the accreditation criteria for carrying out transplantation activities, namely donation, testing, evaluation, procurement, preservation, distribution, transport and transplantation.

Article 143

(1) The competent authorities in the field of transplantation activity in Romania are the National Transplant Agency and the Ministry of Health, through the health control structure.
(on 30-09-2015, Alin. (1) of Article 143 was amended by CORRIGENDUM No 95 of 14 April 2006, published in the OFFICIAL MONITOR No 732 of 30 September 2015.)
(2) The coordination, supervision, approval and implementation of any provisions on transplantation activity shall be the responsibility of the National Transplant Agency.
(on 30-09-2015, Alin. (2) of Art. 143 was amended by CORRIGENDUM No. 95 of 14 April 2006, published in the OFFICIAL MONITOR No. 732 of 30 September 2015.)
(3) The inspection and control measures concerning the transplantation activity shall be carried out by the Ministry of Health, through the health control structure.

(4) The procurement of organs, tissues and cells of human origin shall be carried out in accredited public or private health facilities. The accreditation criteria shall be established by the National Transplant Agency and approved by order of the Minister of Health.
(on 30-09-2015, Alin. (4) of Art. 143 was amended by CORRIGENDUM No. 95 of 14 April 2006, published in the OFFICIAL MONITOR No. 732 of 30 September 2015.)
(5) Transplantation of organs, tissues and cells of human origin shall be carried out in accredited public or private transplant centres. The accreditation issued shall specify the type or types of transplantation that the transplant centre in question may carry out. The accreditation criteria are established by the National Transplant Agency and approved by order of the Minister of Health.
(on 30-09-2015, Alin. (5) of Art. 143 was amended by CORRIGENDUM No. 95 of 14 April 2006, published in the OFFICIAL MONITOR No. 732 of 30 September 2015.)
(6) At all stages of the transplantation chain, from donation to actual transplantation or, where appropriate, to the destruction of unused/unusable organs, tissues and cells, only qualified and competent personnel who have received specialised professional training in the field may be involved.
(7) The National Registry of Voluntary Haematopoietic Stem Cell Donors is the institution responsible for processing applications, from home or abroad, for the use of haematopoietic stem cells from unrelated donors.
(8) In order to achieve the interconnection with similar international institutions, as well as for the accreditation of the National Register of Voluntary Haematopoietic Stem Cell Donors provided for in paragraph 1, the following shall be established (7) and the immunogenetics and histocompatibility (HLA) laboratories, the registry may pay annual fees and dues.
(8^1) In order to achieve interconnection with similar international institutions and/or international organ exchange organisations, the National Transplant Agency may pay annual fees and charges.
(on 03-09-2021, Article 143 of Chapter I, Title VI was supplemented by Point 15, Article I of ORDINANCE No. 18 of 30 August 2021, published in the OFFICIAL MONITOR No. 834 of 31 August 2021)
(9) The level of dues and fees referred to in paragraph. (8) and (8^1) shall be approved annually by Government decision and shall be provided from the state budget through the budget of the Ministry of Health.
(on 03-09-2021, Paragraph (9) of Article 143 , Chapter I , Title VI was amended by Paragraph 16, Article I of ORDINANCE No. 18 of 30 August 2021, published in the OFFICIAL MONITOR No. 834 of 31 August 2021)

Chapter II Donation and the donor of organs, tissues and cells of human origin
Article 144
(1) The removal of organs, tissues and cells of human origin from a living donor shall be carried out under the following conditions:
(a) the removal of organs, tissues and cells of human origin for therapeutic purposes may be carried out from living adult persons of full legal capacity after obtaining their informed, written, free, prior and express consent, in accordance with the model form approved by order of the Minister of Health. The removal of organs, tissues and cells from persons without discernment is prohibited;
b) consent shall be signed only after the donor has been informed by the doctor, social worker or other persons with specialist training of the possible physical, psychological, family, professional and social risks and consequences resulting from the act of removal;
(c) the donor may revoke the consent given up to the time of procurement;
(d) the removal and transplantation of organs, tissues and cells of human origin as a result of physical or moral coercion of a person shall be prohibited;
(e) the donation and transplantation of organs, tissues and cells of human origin may not be the subject of legal acts and deeds for the purpose of obtaining material or other benefits;
f) the donor and the recipient shall sign an authentic instrument declaring that the donation is made for humanitarian purposes, is altruistic in nature and is not the object of legal acts and deeds for the purpose of obtaining material or other benefit, in accordance with the model form approved by order of the Minister of Health;
g) the donor will be exempted from the payment of the hospitalisation/hospitalizations related to the donation, as well as the costs related to the periodic post-donation medical check-ups.

(2) Procurement and transplantation centres shall keep a record of the living donors who have donated in the centre concerned, in accordance with national provisions on the protection of personal data and statistical confidentiality.
(3) Monitoring of living donors shall include mandatory periodic health checks to be carried out at 1 month, 3 months, 6 months and 1 year post-donation, and thereafter when justified.

Article 145

(1) The removal of organs, tissues and cells from living potential minor donors shall be prohibited, except as provided for in this Law.
(2) By way of exception to the provisions of para. (1), if the donor is a minor and is related up to the fourth degree to the recipient, the collection of medullary or peripheral hematopoietic stem cells shall be performed under the following conditions:
(a) the collection of bone marrow or peripheral hematopoietic stem cells from minors may be carried out only with the consent of the minor, if the minor has reached the age of 10, and with the written consent of the legal guardian, i.e. the parents, guardian or curator, in accordance with the model form approved by order of the Minister of Health. If the minor has not reached the age of 10, the sample may be taken with the consent of the legal guardian;
b) in the case of a donor who is at least 10 years of age, the donor's written or verbal consent shall be expressed before the president of the court in whose territorial district the centre where the transplant is to be carried out is located or the court in whose territorial district the donor resides, after a mandatory psychosocial investigation has been carried out by the General Directorate for Social Assistance and Child Protection.
(3) The written or verbal refusal of the minor prevents any removal.

Article 146

(1) The removal of organs, tissues or cells from the living donor shall be carried out with the opinion of the committee for the approval of the donation from the living donor, established within the hospital where the transplantation is carried out; this committee shall evaluate the motivation of the donation and shall control the respect of the patients' rights, according to the model form approved by order of the Minister of Health.
(2) The committee for the approval of the donation from the living donor will have the following composition: a physician with training in bioethics from the county or Bucharest municipality medical college, a psychologist or a psychiatrist and a primary physician, employed by the hospital and having management duties within the hospital, not involved in the transplant team.
(3) This committee will function according to a regulation issued by the National Transplant Agency, in consultation with the Bioethics Committee of the Ministry of Health. The regulation will be approved by order of the Minister of Health.
(on 30-09-2015, Alin. (3) of Art. 146 was amended by CORRIGENDUM No. 95 of 14 April 2006, published in the OFFICIAL MONITOR No. 732 of 30 September 2015.)
(4) The Commission shall evaluate both the donor and the recipient, who shall undergo a psychological and/or psychiatric examination, the purpose of which shall be to test the capacity for exercise and to determine the motivation for donation.
(5) The psychological/psychiatric examination will be carried out by a specialist psychologist or psychiatrist, independent of both the transplant team and the families of the donor and the recipient.
(6) The collection from living donors of blood, skin, sperm, femoral head, placenta, umbilical cord blood, amniotic membranes, to be used for therapeutic purposes, shall be carried out in compliance with the bioethical rules contained in the regulations of the commission for approval of donation from living donors, without the need for the opinion of this commission.
(7) In the case of collection of placental blood, blood samples, skin, sperm, femoral head, placenta, amniotic membrane, cord blood and cord tissue at birth, the number of the document of accreditation or approval of the bank by the National Transplant Agency shall be added to the authorization.
(on 30-09-2015, Alin. (7) of Art. 146 was amended by CORRIGENDUM No. 95 of 14 April 2006, published in the OFFICIAL MONITOR No. 732 of 30 September 2015.)
(8) Donor and recipient data, including genetic information, to which third parties may have access, shall be communicated anonymously so that neither the donor nor the recipient can be identified.
(9) If the donor does not wish to disclose his/her identity, the confidentiality of the donation will be respected, except where disclosure of identity is required by law.

Article 147

The removal of organs, tissues and cells from the deceased donor is carried out under the following conditions:

1. a deceased donor without cardiac activity is defined as a person who has been found to have irreversible and unresuscitable cardiorespiratory arrest, confirmed in hospital by 2 primary physicians. The confirmation of the deceased donor without cardiac activity is made according to the resuscitation protocol, according to the model form approved by order of the Minister of Health, except in the case of unequivocal situations;

2. a deceased donor with cardiac activity is defined as a person who has been found to have irreversibly ceased all brain functions, according to the protocol for the declaration of brain death in accordance with the model form approved by order of the Minister of Health;

3. the declaration of brain death shall be made by physicians who are not members of the teams for coordination, procurement, transplantation of organs, tissues and cells of human origin;

4. the removal of organs, tissues and/or cells from deceased persons shall be carried out only with the written consent of at least one of the adult family members or relatives, in the following order: surviving spouse, parents, descendants, brother/sister, other collateral relative up to and including the fourth degree, according to the model form approved by order of the Minister of Health*);

5. the removal may be carried out without the consent of the family members if, during his/her lifetime, the deceased person has already expressed his/her choice in favour of donation, through a notarial act of consent for removal and registration in the National Register of Organ, Tissue and Cell Donors, according to the model form approved by order of the Minister of Health*);

Note

*) See Order of the Minister of Health No 1.170/2014 approving the model forms for the application of the provisions of Title VI of Law No 95/2006 on health reform, published in the Official Journal of Romania, Part I, No 765 of 22 October 2014.

6. the donation may not be carried out in any form if, during his/her lifetime, the deceased person has already expressed his/her opposition to the donation, by an act of refusal of the donation. The deed of refusal of donation shall be presented by the relatives to the transplant coordinator.

Article 148

(1) The procurement of organs, tissues and cells from living and deceased donors shall be carried out only after a clinical and laboratory examination establishing the compatibility of the donor with the recipient and ruling out any infectious disease, possible contamination or other conditions that pose a risk to the recipient, in accordance with the protocols established for each organ, tissue or cell. In the case of contaminated stem cells, with the exception of HIV, lues and infections resistant to the usual antibiotics, they may be stored at the request of the donor family separately from sterile samples.

(2) The allocation of organs, tissues and cells of human origin, with the exception of haematopoietic stem cells from unrelated donors, collected at national level shall be carried out by the National Transplant Agency, according to the rules established by it on the allocation of organs, tissues and cells of human origin within the Romanian transplant system.

(on 30-09-2015, Alin. (2) of art. 148 was amended by the corrigendum no. 95 of 14 April 2006, published in the OFFICIAL MONITOR no. 732 of 30 September 2015.)

(3) If there is no compatible recipient of organs, tissues and cells of human origin available on the national territory, they may be allocated to the international transplant network, on the basis of an authorisation issued by the National Transplant Agency, according to the model form approved by order of the Minister of Health**).

(on 30-09-2015, Alin. (3) of Art. 148 was amended by CORRIGENDUM No 95 of 14 April 2006, published in the OFFICIAL MONITOR No 732 of 30 September 2015.)

(4) Tissues and cells of human origin harvested may be used immediately for transplantation or may be processed and stored in tissue and cell banks accredited or approved by the National Transplant Agency.

(on 30-09-2015, Alin. (4) of Art. 148 was amended by CORRIGENDUM No 95 of 14 April 2006, published in the OFFICIAL MONITOR No 732 of 30 September 2015.)

(5) Transplantation of tissues or cells of human origin shall be performed only from banks accredited or approved by the National Transplant Agency.

(on 30-09-2015, Alin. (5) of Art. 148 was amended by CORRIGENDUM No. 95 of 14 April 2006, published in the OFFICIAL MONEYL No. 732 of 30 September 2015.)

(6) Each removal of an organ, tissue or cell of human origin from a deceased donor shall be immediately notified and registered in the National Transplant Register at the National Transplant Agency, according to the procedures established by order of the Minister of Health**); in the case of living donors, these data shall be reported to the National Transplant Agency every 6 months.
(on 30-09-2015, Alin. (6) of Art. 148 was amended by CORRIGENDUM No 95 of 14 April 2006, published in the OFFICIAL MONITOR No 732 of 30 September 2015.)
Note
**) See Order of the Minister of Health No 477/2009 on the establishment of the National Transplant Register, the designation of persons responsible for managing data in the National Transplant Register in health units accredited to perform organ transplantation and the establishment of the data required for the registration of a person for the assignment of the unique registration code at the National Transplant Agency, published in the Official Gazette of Romania, Part I, No 322 of 14 May 2009, with subsequent amendments and additions.
(7) Physicians who performed the removal of organs and tissues from a deceased person shall ensure the restoration of the corpse and its physiognomy by specific care and means, including surgery, if necessary, in order to obtain a dignified appearance of the deceased's body.
(8) The removal of organs, tissues and cells of human origin, in forensic cases, shall be done only with the consent of the forensic physician and shall not compromise the result of the forensic autopsy, according to the model form approved by order of the Minister of Health***).
Note
***) See asterisk in Article 147.
(9) The introduction into or removal from the country of organs, tissues, cells of human origin, with the exception of hematopoietic stem cells, shall be made only on the basis of the authorization issued by the National Transplant Agency, according to the model form approved by the order of the Minister of Health, in accordance with customs legislation.
(on 30-09-2015, Alin. (9) of Art. 148 was amended by CORRIGENDUM No 95 of 14 April 2006, published in the OFFICIAL MONITOR No 732 of 30 September 2015.)
(10) The import and export of haematopoietic cells shall be based on the authorisation issued by the National Register of Voluntary Haematopoietic Stem Cell Donors.
(11) The reporting of the authorisations issued by the National Transplant Agency to the Ministry of Health shall be done annually in the activity report or at the request of the Minister of Health.
(on 30-09-2015, Alin. (11) of Art. 148 was amended by CORRIGENDUM No. 95 of 14 April 2006, published in the OFFICIAL MONITOR No. 732 of 30 September 2015.)
(12) It is prohibited to disclose any information on the identity of the cadaveric donor as well as the recipient, except in cases where the donor's family and the recipient respectively agree, as well as in cases where the declaration of identity is required by law. Data on the donor and the recipient, including genetic information, to which third parties may have access will be communicated anonymously so that neither the donor nor the recipient can be identified. Any unauthorised access to data or systems that make it possible to identify donors or recipients shall be penalised in accordance with the legal regulations in force.
(13) Accredited health facilities implementing the National Transplant Programme may pay for funeral services and/or transport of the corpse in the case of donors from whom organs and/or tissues and/or cells have been removed, within the limit of the funds allocated.
(14) After each removal of organs, tissues and/or cells from cadaveric donors, the Donor Declaration Form and the Organ and Tissue Removal Form shall be completed with the data from the time of removal, according to the model form approved by order of the Minister of Health*).
Note
*) See asterisk in Article 147.
(15) The State Health Inspection Structure of the Ministry of Health shall establish together with the National Transplant Agency a vigilance system for reporting, investigating, recording and transmitting information on severe adverse incidents and severe adverse reactions occurring at any stage of the chain from donation to transplantation, approved by order of the Minister of Health**).
(on 30-09-2015, Alin. (15) of Art. 148 was amended by CORRIGENDUM No 95 of 14 April 2006, published in the OFFICIAL MONEYL No 732 of 30 September 2015.)
Note

**) See Order of the Minister of Health No 1.155/2014 for the approval of the Rules on the national application of a rapid alert system in the field of transplantation of organs, tissues and cells of human origin, published in the Official Journal of Romania, Part I, No 771 of 23 October 2014.
(16) The State Health Inspectorate of the Ministry of Health shall coordinate and organize together with the public health control structures of the county and municipal public health directorates the vigilance system referred to in paragraph (a). (15) for the notification of severe adverse events and severe adverse reactions for human tissues and cells used for therapeutic purposes.
(17) The National Transplant Agency shall coordinate and organise the vigilance system referred to in paragraph 15. (15) for the notification of serious adverse events and reactions to human organs used for therapeutic purposes.
(on 30-09-2015, para. (17) of Art. 148 was amended by CORRIGENDUM No 95 of 14 April 2006, published in the OFFICIAL MONEYL No 732 of 30 September 2015.)
(18) The activity of supervising organ exchanges with third countries may be delegated by the National Transplant Agency to European organ exchange organisations.
(on 30-09-2015, Alin. (18) of Art. 148 was amended by CORRIGENDUM No 95 of 14 April 2006, published in the OFFICIAL MONEYL No 732 of 30 September 2015.)
(19) The National Transplant Agency may conclude agreements with European organ exchange organisations, provided that these organisations ensure compliance with the requirements laid down in 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, delegating to these organisations, inter alia, the following:
(a) carrying out the activities laid down in the framework for quality and safety;
b) specific tasks related to the exchange of organs between Romania and Member States and between Romania and third countries.
(on 30-09-2015, Alin. (19) of Art. 148 was amended by CORRIGENDUM No 95 of 14 April 2006, published in the OFFICIAL MONITOR No 732 of 30 September 2015.)

Chapter III Transplantation of organs, tissues and cells of human origin
Article 149
Transplantation of organs, tissues and cells of human origin shall be carried out for therapeutic purposes only.
Article 150
Transplantation of organs, tissues and cells of human origin shall be carried out with the written consent of the recipient, after the recipient has been informed of the risks and benefits of the procedure, in accordance with the model form approved by order of the Minister of Health.
Article 151
(1) If the recipient is unable to give his consent, it may be given in writing by a family member or his legal representative, in accordance with the model form approved by order of the Minister for Health.
(2) In the case of a recipient who is unable to give consent, the transplantation may be carried out without the consent referred to above if, owing to objective circumstances, it is not possible to contact the family or the patient's legal representative in good time and the delay would inevitably lead to the patient's death.
(3) The situation described in para. (2) shall be recorded by the head physician and the patient's attending physician in the form approved by order of the Minister of Health.
Article 152
By way of exception to the provisions of Article 150, in the case of minors or persons lacking legal capacity, consent shall be given by their parents or other persons legally responsible for them, as appropriate, in accordance with the model form approved by order of the Minister for Health*).
Note
*) See asterisk in Article 147.

Chapter IV Financing of transplantation activity
Article 153
The cost of investigations, hospitalisation, surgery, medicines, medical supplies, post-operative care and expenses related to transplant coordination may be settled as follows:

a) from the budget of the Single National Health Insurance Fund, for patients included in the National Transplant Programme;
b) from the state budget and from the Ministry of Health's own revenues, for patients included in the National Transplant Programme;
c) by the patient's personal contribution or, for the patient, by a voluntary health insurance scheme;
d) from donations and sponsorships from natural or legal persons, non-governmental organisations or other interested bodies.

Chapter V Penalties

Article 154

(1) The removal or transplantation of organs, tissues or cells of human origin from living donors without consent given in accordance with the law shall constitute a criminal offence and shall be punishable by imprisonment for a term of 2 to 7 years and disqualification from certain rights.
(2) Attempt shall be punishable.

Article 155

Taking a sample when it compromises a forensic autopsy, requested under the law, shall constitute an offence and shall be punishable by imprisonment for a term of six months to three years or a fine.

Article 156

(1) It shall be an offence to donate organs, tissues or cells of human origin for the purpose of obtaining material gain for oneself or for another person and shall be punishable by imprisonment for a term of three months to two years or by a fine.
(2) Coercing a person to donate organs, tissues or cells of human origin shall constitute a criminal offence and shall be punishable by imprisonment for a term of 2 to 7 years and disqualification.
(3) The publication or publicity of advertisements for the donation of organs, tissues or cells of human origin, which donation would be carried out for the purpose of obtaining material gain for oneself or for another person, shall constitute an offence and shall be punishable by imprisonment for a term of 6 months to 3 years or a fine.

Article 157

(1) Organising or carrying out the removal of organs, tissues or cells of human origin for transplantation with the aim of obtaining material benefit for the donor or organiser shall constitute a criminal offence and shall be punishable by imprisonment from 2 to 7 years and disqualification.
(2) The penalty provided for in paragraph 1 shall be (1) the purchase of organs, tissues or cells of human origin for the purpose of resale shall also be punishable.
(3) Attempt shall be punishable.

Article 158

(1) The introduction into or removal from the country of organs, tissues or cells of human origin without a special authorisation issued by the National Transplantation Agency shall constitute a criminal offence and shall be punishable by imprisonment for a term of 2 to 7 years and disqualification.
(on 30-09-2015, Alin. (1) of Art. 158 was amended by the AMENDMENT No. 95 of 14 April 2006, published in the OFFICIAL MONITOR No. 732 of 30 September 2015.)
(2) Attempt shall be punishable.

Chapter VI Transitional and final provisions

Article 159

(1) Procurement and transplantation of organs, tissues and cells of human origin shall be carried out by medical specialists in public or private health facilities. The list of accredited public or private health facilities shall be published on the website of the National Transplant Agency and shall be continuously updated.
(on 30-09-2015, Alin. (1) of Art. 159 was amended by the corrigendum No. 95 of 14 April 2006, published in the OFFICIAL MONITOR No. 732 of 30 September 2015.)
(2) Accreditation in the field of transplantation of public or private health establishments is valid for 5 years. Any change in the initial accreditation criteria in accredited units shall be notified within 5 days to the National Transplant Agency for reaccreditation.
(on 30-09-2015, Alin. (2) of Art. 159 was amended by the corrigendum No 95 of 14 April 2006, published in the OFFICIAL MONITOR No 732 of 30 September 2015.)

(2^1) In cases duly justified by the health unit, following the evaluation for accreditation and to the extent that the accreditation criteria are not fully met by the health units, the National Transplant Agency may accredit, according to the law, a health unit for the activity of tissue bank and user, based on its submission of a compliance plan with precisely specified responsibilities and implementation deadlines.
(on 13-11-2018, Article 159 of Chapter VI , Title VI was supplemented by Article I of the EMERGENCY ORDINANCE No. 95 of 9 November 2018, published in the OFFICIAL MONITOR No. 959 of 13 November 2018)
Note
According to Article II of the EMERGENCY ORDINANCE No 95 of 9 November 2018, published in the OFFICIAL MONITOR No 959 of 13 November 2018, in order to ensure the continuity of transplant activities, the National Transplant Agency may grant, upon request, temporary accreditation for a period of 6 months to health units whose accreditation has expired or is due to expire by the end of 2018, until the completion of the evaluation procedures for reaccreditation, subject to the submission of documents proving that the accreditation criteria have been met, in accordance with Article 5(5). (3) lit. a) - c) of the Order of the Minister of Health no. 1.527/2014.
(3) The criteria for accreditation of the health units referred to in para. (1) shall be proposed by the National Transplant Agency and approved by order of the Minister of Health*), in accordance with the European legislation in this field.
(as of 30-09-2015, para. (3) of Art. 159 was amended by CORRIGENDUM No. 95 of 14 April 2006, published in the OFFICIAL MONITOR No. 732 of 30 September 2015.)
Note
*) See Order of the Minister of Health No 1.527/2014 on the methodological rules for the application of Title VI "Performance of removal and transplantation of organs, tissues and cells of human origin for therapeutic purposes" of Law No 95/2006 on health reform, published in the Official Gazette of Romania, Part I, No 951 of 29 December 2014.
(4) The National Transplant Agency may suspend the activity or revoke the accreditation, if following the evaluations carried out by the representatives of the National Transplant Agency, as well as upon referral to the health inspectors, it is found that the health facility in question does not comply with the legal provisions in force.
(on 30-09-2015, Alin. (4) of Art. 159 was amended by the corrigendum No 95 of 14 April 2006, published in the OFFICIAL MONITOR No 732 of 30 September 2015.)
(5) Accredited health facilities shall establish a system for identifying each donation act, by means of a unique code, and each product associated with it. Coded labelling is required for organs, tissues and cells, enabling a link to be established from donor to recipient and vice versa. The information will be kept for at least 30 years in paper or electronic form.
(6) Health care establishments accredited for the processing and/or use of tissues and/or cells shall keep a record of their activity, including the types and quantities of tissues and/or cells procured, tested, preserved, stored, distributed or discarded, and the origin and destination of these tissues and/or cells for human use. They will send an annual activity report to the National Transplant Agency, which will be published both on their own website and on the website of the National Transplant Agency. The provisions of this paragraph shall also apply accordingly to organ transplantation.
(on 30-09-2015, Alin. (6) of Art. 159 was amended by CORRIGENDUM No. 95 of 14 April 2006, published in the OFFICIAL MONEYL No. 732 of 30 September 2015.)
(7) The National Transplant Agency shall manage the national registers, which ensure continuous monitoring of transplant activity, activities of procurement centres and transplant centres, including the total number of living and deceased donors, types and number of organs procured and transplanted or destroyed, in accordance with the national provisions on personal data protection and confidentiality of statistical data.
(on 30-09-2015, Alin. (7) of Art. 159 was amended by CORRIGENDUM No 95 of 14 April 2006, published in the OFFICIAL MONEYL No 732 of 30 September 2015).
(8) The National Transplant Agency shall establish and maintain an up-to-date register of procurement centres and transplant centres and provide information on request.
(on 30-09-2015, Alin. (8) of Art. 159 was amended by CORRIGENDUM No 95 of 14 April 2006, published in the OFFICIAL MONEYL No 732 of 30 September 2015.)

(9) The National Transplant Agency shall report to the European Commission every 3 years on the activities undertaken in relation to the provisions of Directive 2010/53/EU and on the experience gained from its implementation.
(on 30-09-2015, Alin. (9) of Art. 159 was amended by CORRIGENDUM No 95 of 14 April 2006, published in the OFFICIAL MONEYL No 732 of 30 September 2015).
(10) The National Registry of Voluntary Hematopoietic Stem Cell Donors methodologically coordinates the activities of recruitment, testing and donation of hematopoietic stem cells from unrelated donors is responsible for auditing the activities it coordinates and for implementing the Single Coding and Labeling System in accordance with the European coding requirements in the donation activity for transplantation of hematopoietic stem cells from unrelated donors.

Article 160

Health establishments accredited for tissue and/or cellular transplantation activity shall be required to designate a person responsible for ensuring the quality of the tissues and/or cells processed and/or used in accordance with the relevant European and Romanian legislation. The professional training standard of this person will be established by rules.

Article 161

The methodological rules for the application of this Title shall be drawn up within 90 days of the publication of the law and shall be approved by order of the Minister of Health**).

Note

**) See asterisk in Article 159.

Article 162

On the date of entry into force of this Title, Law No 2/1998 on the Procurement and Transplantation of Human Tissues and Organs, published in the Official Journal of Romania, Part I, No 8 of 13 January 1998, as subsequently amended, and Article 17(1)(a) and (b) of Law No 2/1998, as amended, shall apply. (3), Art. 21, 23 and 25 of Act No. 104/2003 on the handling of human cadavers and the removal of organs and tissues from cadavers for transplantation, published in the Official Journal of Romania, Part I, No. 222 of 3 April 2003, as subsequently amended and supplemented, shall be repealed.

*

(3), Art. 5 para. (1), Art. 9 para. (1), Art. 10, Art. 11 para. (1), Art. 12-16, Art. 17 para. (1), Art. (2) (b), (g) and (h), Art. 18 para. (1) (a) and (c), Art. 20 para. (1), Articles 21-23 and 31 of 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.