Criteria for the selection of cell, tissue, and organ donors, list of precluding circumstances for the donation of cells, tissues, or organs, list of mandatory laboratory studies established for a donor, and the conditions and procedure for carrying out these studies

Passed 18.03.2015 No. 12
RT I, 20.03.2015, 3
Entry into force 23.03.2015

Amended by the following acts

<table>
<thead>
<tr>
<th>Passed</th>
<th>Published</th>
<th>Entry into force</th>
</tr>
</thead>
<tbody>
<tr>
<td>22.10.2015</td>
<td>RT I, 27.10.2015, 9</td>
<td>30.10.2015</td>
</tr>
</tbody>
</table>

The Regulation will be established in accordance with subsection 10 (2) and (5) of the Procurement, Handling and Transplantation of Cells, Tissues and Organs Act and subsection 15 (3) of the Communicable Diseases Prevention and Control Act.

§ 1. Scope of regulation

(1) This Regulation establishes the criteria for the selection of cell, tissue, and organ donors, the list of precluding circumstances for the donation of cells, tissues, or organs, the list of mandatory laboratory studies established for a donor, and the conditions and procedure for carrying out these studies.

(2) The requirements established with this Regulation are applied for the selection of germ cell donors, except in the case described in subsection 3 (3) of this Regulation.

§ 2. Definitions

(1) For the purposes of this Regulation, an allogeneic donor is a person from whom cells, tissues, or organs are removed, and used for transplantation to another person.

(2) For the purposes of this Regulation, an autologous donor is a person from whom cells and tissues are removed, and used for transplantation to the same person.

(3) For the purposes of this Regulation, partner donation means the donation of germ cells between a man and a woman who disclose that they are in an intimate relationship.

(4) For the purposes of this Regulation, direct use means a situation in which cells or tissues are donated, and they are used for transplantation without preservation.

(5) For the purposes of this Regulation, indirect use means a situation in which cells or tissues are donated, and they are preserved before the transplantation.

(6) For the purposes of this Regulation, a transplant is the cell, tissue, or an organ intended to be transplanted.

§ 3. The basic criteria for donor selection

(1) The evaluation of circumstances which may endanger the health of the donor and recipient, and the quality and safety of the cells, tissues, and organs being donated shall be documented when selecting a donor.
(2) The suitability of a person for donation is determined on the basis of the form completed by the person, an interview, the physical examination of the person, their anamnesis, their prior risk behaviour, laboratory studies, a post-mortem examination in the case of a deceased donor, and any other relevant studies. In the case of a deceased donor, an interview is conducted with the persons established in subsection 17 (3) and subsection 18 (1) of the Procurement, Handling and Transplantation of Cells, Tissues and Organs Act.

(3) The criteria for the selection of donors is not applied for autologous donors and partner donations. In case the removed cells and tissues are to be preserved or processed, the studies established in section 7 of this Regulation (except genetic studies) shall be carried out.

(4) In the handling of cells and tissues from autologous donors and germ cells from partner donations, laboratory studies shall be carried out to identify the markers of infectious agents for informational purposes in order to avoid the risk of cross-contamination and threat to the handler’s personnel. Positive study results do not prevent the preservation, processing, and transplantation of tissues and cells or products derived therefrom if an existing separate preservation system has been developed, which assures the absence of threat of cross-contamination with other transplants, contamination with added substances, and the risk of confusion.

(5) Depending on the cells, tissues, or organs to be donated, and the person’s physical state and state of health, a person shall be deemed to be a donor if consent has been obtained from them, or the person’s alleged will has been established, and there are no criteria provided for in section 4, 5, and 6 of this Regulation.

(6) In a specific case, it is allowed to deviate from the criteria established in section 4, 5, and 6 of this Regulation on the basis of a documented risk analysis carried out by a competent person.

§ 4. List of criteria precluding circumstances for the donation of cells and tissues of a deceased person

A deceased person is excluded from the donation of cells and tissues if an autopsy does not provide information about the cause of their death and the cause of death is unknown, or one of the following criteria is valid:

1) former occurrence of a disease of unknown cause;
2) presence or former occurrence of a malignant tumour, with the exception of primary basal cell carcinoma, cervical carcinoma in situ, and some primary central nervous system tumours which should be evaluated based on scientific evidence. Donors with a malignant tumour may be evaluated and considered for corneal donation with the exception of those who have a retinal tumour, a hematologic tumour, or a malignant tumour in the anterior part of the eye;
3) risk of transmission of diseases caused by prions. The following people are in that risk group:
   a) people who have been diagnosed with the Creutzfeldt-Jakob disease or a variant of the Creutzfeldt-Jakob disease, or people who have a family history of non-iatrogenic Creutzfeldt-Jakob disease;
   b) people who have experienced rapidly evolving dementia or a disease which degenerates the nervous system, including diseases with an unknown origin;
   c) recipients of hormones from the human pituitary gland, recipients of the cornea, sclera, and dura mater, and people who have undergone neurosurgical operations in which dura mater was used;
4) a systematic infection which is not under control during the donation, including bacterial diseases, systemic viral, fungal, or parasitic infections, or a significant local infection in the cells, tissues, and organs to be donated. Donors with bacterial septicaemia may be evaluated and considered for the donation of eye tissues and cells, but only if the cornea is preserved in an organic culture so that it would be possible to detect the possible bacterial contamination of the tissue;
5) persons with HIV, acute or chronic hepatitis B, except in the case of persons with proven immunity, prior occurrence of hepatitis C and HTVL I/II, clinical signs or the existence of laboratory evidence, risk of transmission of the mentioned infectious diseases, or the discovery of risk factors;
6) prior occurrence of a chronic and systemic autoimmune disease which may have a negative effect on the quality of the cells, tissues, or organs to be removed;
7) absence of a blood test which meets the requirements provided for in section 8 of this Regulation;
8) treatment with immunosuppressive agents if less than 90 calendar days have passed after the termination of the treatment at the moment of the donation of cells, tissues, or organs;
9) physical signs detected during the physical examination of the donor’s body, which suggest the risk of transmission of infectious diseases;
10) exposure to cyanide, lead, mercury, gold, or any other substance which may be passed to the recipient in an amount which endangers their health;
11) recent vaccination with an attenuated live virus, for which the risk of transmission is considered;
12) transplantation, in which case xenotransplantation was used.

§ 5. List of criteria precluding the donation of cells, tissues, and organs of a live donor

1) The criteria established in section 4 of this Regulation for the exclusion of a deceased person from the donation of cells and tissues are applied for the exclusion of a live person from the donation of cells, tissues, or organs.

2) Depending on the cells, tissues, or organs being donated, the handler may establish additional criteria for the exclusion from live donation.
§ 6. List of criteria precluding from the donation of a person’s germ cells

(1) A person is excluded from the donation of germ cells if they have one of the following:
1) HIV;
2) acute or chronic hepatitis B with the exception of persons with an identified immunity;
3) hepatitis C;
4) syphilis;
5) chlamydia infection;
6) HTLV I/II;
7) cystic fibrosis and other autosomal recessive diseases;
8) fragile-X Syndrome, and other X-linked recessive disorders;
9) other genetic diseases;
10) multifactorial congenital disorder or syndrome;
11) chromosome changes which might likely cause unbalanced chromosome changes.

(2) In the case of germ cell donors, a genetic screening of autosomal recessive genes causing hereditary diseases known in the donor’s family history or hereditary diseases caused by the donor’s ethnic background shall be carried out in order to evaluate the risk of transmission of diseases. All information about the risks associated with hereditary diseases and the measures to be taken to avoid these risks shall be communicated to the recipient.

§ 7. List of mandatory laboratory studies established for a donor

(1) The minimum requirements for the donor include laboratory studies for the detection of the following markers of infectious agents:
1) HIV-1, 2 antibodies to detect HIV-1 and HIV-2;
2) HBs antigen and HBC antibodies for the detection of hepatitis B;
3) HBV antibodies for the detection of hepatitis C;
4) Treponema pallidum antibodies for the detection of active syphilis;
5) a study of antibodies shall be carried out for the detection of HTVL I/II with donors who themselves or whose sexual partners live or originate from a high-prevalence area, or donors whose parents originate from the mentioned area.

(2) In the case of germ cell donors, studies for the detection of Neisseria gonorrhoeae, Trichomonas vaginalis, and Chlamydia trachomatis, a chromosomal study of peripheral blood, and a molecular-genetic testing for cystic fibrosis shall also be carried out in addition to the studies specified in subsection 1 of this section.

(3) In the case of egg cell donors, studies for the fragile X syndrome shall also be carried out in addition to the studies specified in subsections 1 and 2 of this section.

(4) If the HBc antibodies are positive and the HBs antigen is negative, further studies with a risk evaluation shall be carried out in order to determine whether the cells, tissues, or organs meet the requirements of clinical use.

(5) Depending on the risk analysis, the handler may carry out additional laboratory studies on the germ cell donor for pathogens and genetic diseases which may be transmitted.

§ 8. The conditions and procedure for carrying out laboratory studies

(1) If the donor has lost blood and there has been a transfer of blood, blood components, or colloids to them within 48 hours before the collection of a blood sample, or crystalloids have been transferred to them within an hour before taking the blood sample, the blood sample may be invalid due to the blood dilution. In that case, the dilution level of the blood samples shall be evaluated. Handlers may accept cells, tissues, and organs from donors with a plasma dilution level of more than 50% only if the used study method has been validated for the plasma dilution, or if there is a blood sample taken before the transfer.

(2) In the case of deceased donors, the blood sample shall be taken immediately before death or no later than within 24 hours after the person has died.

(3) In the case of live donors, with the exception of bone marrow stem cell and peripheral blood stem cell donors, blood samples for laboratory studies have to be collected during the procurement or within seven days after the procurement. If it possible to preserve the live donor’s cells and tissues for a long time, a re-sample and study have to be performed after 180 days have passed. If the blood sample is further studied with a nucleic acid amplification technique for HIV, HBV, and HCV, the re-study does not have to be carried out. The re-study may also be omitted if the processing for the named viruses included a validated inactivation stage.

[RT I, 27.10.2015, 9 – entry into force. 30.10.2015]
(4) For the procurement of bone marrow and peripheral blood stem cells, the blood sample for the study has to be collected within 30 days before the procurement.

(5) For the donation of germ cells, the blood sample shall be collected for genetic studies during the donation, with the exception of partner donation.

(6) In the case of partner donation (indirect usage), the blood samples shall be collected within three months before the first donation. Regarding the following donations from the same donors, the blood samples shall be collected no later than within 24 months since the last sample was collected.

(7) Donations of spermatozoa, with the exception of partner donations, are quarantined for at least 180 days after which a re-study shall be carried out. If the blood sample is further studied with a nucleic acid amplification technique for HIV, HBV, and HCV, the re-study does not have to be carried out. The re-study may also be omitted if the processing for the named viruses included a validated inactivation stage. [RT I, 27.10.2015, 9 – entry into force: 30.10.2015]

(8) The blood samples established in subsection 2, 3, 5, and 6 of this section are studied on the basis of the donor’s serum or plasma, and these may not be replaced with studies made with other fluids or secretions, unless it is specifically clinically substantiated, and a laboratory study is used which is validated for that fluid.

(9) Transplantation of embryos created from donor egg cells is allowed without prior quarantine if the recipient has provided their consent in writing.