

L.N. 345 of 2012

**HUMAN BLOOD AND TRANSPLANTS ACT
(CAP. 483)**

Organ Transplants (Quality and Safety) Regulations, 2012

BY virtue of the powers conferred by article 16 of the Human Blood and Transplants Act, the Minister for Health, the Elderly and Community Care, after consultation with the Licensing Authority, has made the following regulations:-

1. (1) The title of these regulations is the Organ Transplants (Quality and Safety) Regulations, 2012. Title and scope.

(2) The scope of these regulations is to transpose the European Parliament and Council Directive 2010/53/EU of 7 July 2010 on standards of quality and safety of human organs intended for transplantation.

2. In these regulations unless the context otherwise requires: Interpretation.

"authorisation" means authorisation, accreditation, designation, licensing or registration;

"disposal" means the final placement of an organ where it is not used for transplantation;

"donation" means donating organs for transplantation;

"donor" means a person who donates one or several organs, whether donation occurs during lifetime or after death;

"donor characterisation" means the collection of the relevant information on the characteristics of the donor needed to evaluate such person's suitability for organ donation, in order to undertake a proper risk assessment and minimise the risks for the recipient, and optimise organ allocation;

"European organ exchange organisation" means a non-profit organisation, whether public or private, dedicated to national and cross-border organ exchange, in which the majority of its member countries are Member States;

"operating procedures" means written instructions describing the steps in a specific process, including the materials and methods to be used and the expected end outcome;

"organ" means a differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to develop physiological functions with a significant level of autonomy. A part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirements of structure and vascularisation;

"organ characterisation" means the collection of the relevant information on the characteristics of the organ needed to evaluate its suitability, in order to undertake a proper risk assessment and minimise the risks for the recipient, and optimise organ allocation;

"preservation" means the use of chemical agents, alterations in environmental conditions or other means to prevent or retard biological or physical deterioration of organs from procurement to transplantation;

"procurement" means a process by which the donated organs become available;

"procurement organisation" means a healthcare establishment, a team or a unit of a hospital, a person, or any other body which undertakes or coordinates the procurement of organs, and is authorised to do so by the Authority under the regulatory framework in the Member State concerned;

"recipient" means a person who receives a transplant of an organ;

"serious adverse event" means any undesired and unexpected occurrence associated with any stage of the chain from donation to transplantation that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity;

"serious adverse reaction" means an unintended response, including a communicable disease, in the living donor or in the recipient that might be associated with any stage of the chain from donation to transplantation that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity;

"traceability" means the ability to locate and identify the organ at each stage in the chain from donation to transplantation or disposal, including the ability to:

- identify the donor and the procurement organisation,

- identify any recipient at any transplantation centre,

and locate and identify all relevant non-personal information relating to products and materials coming into contact with that organ;

"transplantation" means a process intended to restore certain functions of the human body by transferring an organ from a donor to a recipient;

"transplantation centre" means a healthcare establishment, a team or a unit of a hospital or any other body which undertakes the transplantation of organs and is authorised to do so by the Authority under the regulatory framework in the Member State concerned.

3. (1) The Superintendent of Public Health shall be the Licensing Authority for the purposes of these regulations. The Licensing Authority.

(2) The Licensing Authority, hereinafter referred to as "the Authority", shall have the following functions:

- (a) to ensure that procurement organisations and transplantation centres have in place a framework for quality and safety in accordance with regulation 4;

- (b) to indicate to the procurement organisations and transplantation centres which activities they may undertake;

- (c) to establish conditions applicable to procurement organisations and transplantation centres;

- (d) to issue, renew, amend, vary, suspend or revoke any licence that may be required by or under these regulations;

- (e) to carry out inspections of procurement organisations, conditions of procurement and transplantation centres and to organize control measures in such procurement organisations and transplantation regularly and in any case not less than once every two years;

- (f) to grant, suspend, or withdraw, as appropriate, the authorisations of procurement organisations or transplantation centres or prohibit procurement organisations or transplantation centres from carrying out their activities where control measures demonstrate that such organisations or centres are not complying with the requirements of these regulations;

(g) to establish guidelines concerning the conditions of the inspections and control measures, and on the training and qualification of the officials involved in order to reach a consistent level of competence and performance;

(h) to put in place a reporting system and management procedure for serious adverse events and reactions as provided for in regulation 11(1) and (2);

(i) to issue appropriate guidance to healthcare establishments, professionals and other parties involved in all stages of the chain from donation to transplantation or disposal, which may include guidance for the collection of relevant post-transplantation information to evaluate the quality and safety of the organs transplanted;

(j) supervise organ exchange with other Member States and with third countries as provided for in regulation 18(1);

(k) to ensure that the fundamental right to protection of personal data is fully and effectively protected in all organ transplantation activities, in conformity with the Data Protection Act and European Union legal provisions on the protection of personal data, in particular Directive 95/46/EC.

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(3) The Licensing Authority may by rules delegate any of the functions referred to in sub-regulation (2) to any other body it deems competent. Such a body may also assist the Authority in carrying out its functions.

(4) The Licensing Authority shall levy such fees as may be prescribed for the purpose of this Act.

Framework for
quality and
safety.

4. (1) Procurement organisations and transplantation centres shall be bound to have in place a framework for quality and safety covering all stages of the chain from donation to transplantation or disposal.

(2) The framework shall provide for the adoption and implementation of operating procedures for:

(a) the verification of donor identity;

(b) the verification of the details of the donor's or the donor's family's consent, authorisation or absence of any objection, in accordance with the national rules that apply where donation and procurement take place;

(c) the verification of the completion of the organ and donor characterisation in accordance with regulation 7 and the Schedule;

(d) the procurement, preservation, packaging and labelling of organs in accordance with regulations 5, 6 and 8;

(e) the transportation of organs in accordance with regulation 8;

(f) ensuring traceability, in accordance with regulation 10, guaranteeing compliance with European Union and national legal provisions on the protection of personal data and confidentiality;

(g) the accurate, rapid and verifiable reporting of serious adverse events and reactions in accordance with regulation 11(1);

(h) the management of serious adverse events and reactions in accordance with regulation 11(2).

(3) Procurement organisations and transplant centres shall ensure that the healthcare personnel involved at all stages of the chain from donation to transplantation or disposal are suitably qualified or trained and competent, and shall develop specific training programmes for such personnel.

5. Procurement of organs shall take place in, or be carried out by, procurement organisations that comply with the rules laid down in these regulations. Procurement organisations.

6. (1) Medical activities in procurement organisations, such as donor selection and evaluation, shall be performed under the advice and the guidance of a doctor of medicine as referred to in Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications. Requirements for the procurement of human organs.

(2) Procurement shall take place in operating theatres, which are designed, constructed, maintained and operated in accordance with adequate standards and best medical practices so as to ensure the quality and safety of the organs procured.

(3) Procurement materials and equipment shall be managed with due regard to relevant national and international regulations, standards and guidelines covering the sterilisation of medicines and medical devices. Qualified, sterile instruments and procurement devices shall be used for organ procurement.

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Organ and
donor
characterisation.

7. (1) (a) All procured organs and donors thereof shall be characterised before transplantation through the collection of the information set out in the Schedule.

(b) The information specified in Part A of the Schedule contains a set of minimum data which has to be collected for each donation. Information specified in Part B of the Schedule contains a set of complementary data to be collected in addition, based on the decision of the medical team, taking into account the availability of such information and the particular circumstances of the case.

(2) Notwithstanding the provisions of sub-regulation (1), if according to a risk-benefit analysis in a particular case, including in life-threatening emergencies, the expected benefits for the recipient outweigh the risks posed by incomplete data, an organ may be considered for transplantation even where not all of the minimum data specified in Part A of the Schedule are available.

(3) In order to meet the quality and safety requirements laid down in these regulations, the medical team shall endeavour to obtain all necessary information from living donors and for that purpose shall provide them with the information they need in order to understand the consequences of donation. In the case of deceased donation, where possible and appropriate, the medical team shall endeavour to obtain such information from relatives of the deceased donor or other persons. The medical team shall also endeavour to make all parties from whom information is requested aware of the importance of the swift transmission of that information.

(4) The tests required for organ and donor characterisation shall be carried out by laboratories with suitably qualified or trained and competent personnel and adequate facilities and equipment.

(5) Organisations, bodies and laboratories involved in organ and donor characterisation shall have appropriate operating procedures in place to ensure that the information on organ and donor characterisation reaches the transplantation centre in due time.

(6) Where organs are exchanged between Member States, the information on organ and donor characterisation, as specified in the Schedule, shall be transmitted to the other Member State with which the organ is exchanged.

Transport of
organs.

8. (1) The following requirements shall be met during the transportation of organs:

(a) the organisations, bodies or companies involved in

the transportation of organs shall have appropriate operating procedures in place to ensure the integrity of the organs during transport and a suitable transport time;

(b) the shipping containers used for transporting organs shall be labelled with the following information:

(i) identification of the procurement organisation and the establishment where the procurement took place, including their addresses and telephone numbers;

(ii) identification of the transplantation centre of destination, including its address and telephone number;

(iii) a statement that the package contains an organ, specifying the type of organ and, where applicable, its left or right location and marked "HANDLE WITH CARE";

(iv) recommended transport conditions, including instructions for keeping the container at an appropriate temperature and position;

(c) the organs transported shall be accompanied by a report on the organ and donor characterisation.

(2) The requirements laid down in sub-regulation (1)(b) need not be met where the transportation is carried out within the same establishment.

9. (1) Transplantation shall take place in, or shall be carried out by, transplantation centres that are duly authorised. Transplantation centres.

(2) The Licensing Authority shall indicate in the authorisation which activities the transplantation centre concerned may undertake.

(3) The transplantation centre shall verify before proceeding to transplantation that:

(a) the organ and donor characterisation are completed and recorded in accordance with regulation 6 and the Schedule;

(b) the conditions of preservation and transport of shipped organs have been maintained.

(4) The Licensing Authority shall, upon the request of the European Commission or another Member State, provide information on the national requirements for the authorisation of transplantation

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centres.

Traceability.

10. (1) Procurement organisations and transplantation centres shall ensure that:

(a) all organs procured, allocated and transplanted on their territory can be traced from the donor to the recipient and vice versa in order to safeguard the health of donors and recipients;

(b) they have a donor and recipient identification system that can identify each donation and each of the organs and recipients associated with it.

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(2) With regard to such a system, it shall be ensured that confidentiality and data security measures are in place in compliance with the provisions of article 16 of the Data Protection Act.

(3) (a) The bodies involved in the chain from donation to transplantation or disposal shall keep the data needed to ensure traceability at all stages of the chain from donation to transplantation or disposal and the information on organ and donor characterisation as specified in the Schedule, in accordance with the framework for quality and safety.

(b) Data required for full traceability shall be kept for a minimum of thirty years after donation. Such data may be stored in electronic form.

(4) Where organs are exchanged between Member States, the procurement organisations and transplant centres shall transmit the necessary information to ensure the traceability of organs, in conformity with the procedures established by the European Commission pursuant to Article 29 of Directive 2010/53/EU.

Reporting system and management of serious adverse events and reactions.

11. (1) Procurement organisations and transplant centres shall establish and maintain a system to report, investigate, register and transmit relevant and necessary information concerning serious adverse events that may influence the quality and safety of organs and that may be attributed to the testing, characterisation, procurement, preservation and transport of organs, as well as any serious adverse reaction observed during or after transplantation which may be connected to those activities.

(2) Procurement organisations and transplant centres shall have an operating procedure in place for the management of serious adverse events and reactions.

(3) In particular, and with regard to sub-regulations (1) and (2), procurement organisations and transplant centres shall ensure that operating procedures are in place for the notification, in due time, of:

(a) any serious adverse event and reaction to the Licensing Authority and to the concerned procurement organisation or transplantation centre;

(b) the management measures with regard to serious adverse events and reactions to the Authority.

(4) Where organs are exchanged between Member States, the procurement organisations and transplant centres shall ensure that serious adverse events and reactions are reported in conformity with the procedures established by the European Commission pursuant to Article 29 of Directive 2010/53/EU.

(5) Procurement organisations shall, where relevant, ensure the interconnection between the reporting system referred to in sub-regulation (1) and the notification system established in accordance with regulation 8 of the Tissues and Cells (Quality and Safety) Regulations, 2006. L.N. 271 of 2006.

12. (1) Healthcare personnel directly involved in the chain from donation to the transplantation or disposal of organs shall be suitably qualified or trained and competent to perform their tasks and are provided with the relevant training, as referred to in regulation 4(3). Healthcare personnel.

(2) Procurement of organs shall be carried out by persons who have successfully completed a training programme specified by a clinical team specialising in the organs to be procured, or in a centre authorised for procurement.

13. (1) Donations of organs from deceased and living donors shall be voluntary and unpaid. Principles governing organ donation.

(2) The principle of non-payment shall not prevent living donors from receiving compensation, provided it is strictly limited to making good the expenses and loss of income related to the donation. The Authority shall define the conditions under which such compensation may be granted, while avoiding there being any financial incentives or benefit for a potential donor.

(3) It shall be illegal to advertise the need for, or availability of, organs where such advertising is with a view to offering or seeking financial gain or comparable advantage.

(4) A person who engages in an activity to which sub-regulation (3) applies does not commit an offence under that sub-regulation if he is designated by the Licensing Authority as a person who may lawfully engage in the activity.

(5) The procurement of organs shall be carried out on a non-profit basis.

Consent
requirements.

14. (1) The Authority shall lay down the standards expected in relation to the obtaining of consent.

(2) The procurement of organs shall be carried out only after all requirements relating to consent, authorisation or absence of any objection have been met.

(3) The procurement of organs shall be carried out only when:

(a) all prospective organ donors, their relatives or any other person granting consent on behalf of donors, have been given information in accordance with guidelines and authorisation requirements as established by the Authority;

(b) information in accordance with guidelines and authorization requirements established by the Authority has been obtained from all persons who are willing to donate organs, their relatives or any other person granting consent on behalf of donors.

Quality and
safety aspects of
living donation.

15. (1) Procurement organisations and transplant centres shall take all necessary measures to ensure the highest possible protection of living donors in order to fully guarantee the quality and safety of organs for transplantation.

(2) Procurement organisations and transplant centres shall ensure that living donors are selected on the basis of their health and medical history, by suitably qualified or trained and competent professionals. Such assessments may provide for the exclusion of persons whose donation could present unacceptable health risks.

(3) Procurement organisations and transplant centres shall keep and maintain a register or record of the living donors.

(4) Living donors shall be followed up and procurement organisations, transplant centres and institutions responsible for the follow up of living donors shall have a system in order to identify, report and manage any event potentially relating to the quality and safety of the donated organ, and hence of the safety of the recipient, as well as any serious adverse reaction in the living donor that may

result from the donation. Such adverse events and reactions shall be reported to the Authority.

16. (1) Procurement organisations and transplant centres shall ensure that the fundamental right to protection of personal data is fully and effectively protected in all organ donation and transplantation activities, in conformity with the provisions on the protection of personal data laid down in the Data Protection Act.

Protection of personal data, confidentiality and security of processing.
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(2) Procurement organisations and transplant centres shall take all necessary measures to ensure that:

(a) the data processed are kept confidential and secure in accordance with articles 25 and 26 of Data Protection Act; Cap. 440.

(b) donors and recipients whose data are processed within the scope of these regulations are not identifiable, except as permitted by article 15 of the Data Protection Act; Cap. 440.

(c) the principles relating to data quality, as set out in article 7 of the Data Protection Act, are met. Cap. 440.

(3) Procurement organisations and transplant centres shall ensure that:

(a) data security measures are in place, as well as safeguards against any unauthorised data additions, deletions or modifications to donor files or deferral records, and transfer of information;

(b) procedures are in place to resolve data discrepancies;

(c) no unauthorised disclosure of information occurs, whilst guaranteeing the traceability of donations;

(d) the identity of any recipient is not disclosed to the donor or his family and vice-versa;

(e) the information which is collected for the purposes of these regulations is held securely to ensure that -

(i) the information is available for the purpose of tracing donations;

(ii) the information is only disclosed in accordance with an order by the courts, upon request by the Licensing Authority or as permitted by law.

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(4) The medical director responsible for the procurement organisation or the transplantation centre shall ensure that the results of the donor evaluation and testing procedures are documented and any major anomalies are reported to the Licensing Authority.

(5) Any unauthorised accessing of data or systems that makes identification of donor or recipients possible shall be punishable in accordance with regulation 20.

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(6) Any use of systems or data that makes the identification of donors or recipients possible with a view to tracing donors or recipients other than for the purposes permitted by articles 12, 13, 14 and 15 of the Data Protection Act, or as provided in these regulations, shall be punishable in accordance with regulation 20 of these regulations.

Records and reports concerning procurement organisations and transplantation centres.

17. (1) The Licensing Authority shall:

(a) keep a record of the activities of procurement organisations and transplantation centres, including aggregated numbers of living and deceased donors, and the types and quantities of organs procured and transplanted, or otherwise disposed of in accordance with European Union and national legal provisions on the protection of personal data and statistical confidentiality;

(b) draw up and make publicly accessible an annual report on activities referred to in paragraph (a);

(c) establish and maintain an updated record of procurement organisations and transplantation centres.

(2) The Licensing Authority shall, upon the request of the European Commission or another Member State, provide information on the record of procurement organisations and transplantation centres.

Organ exchange with third countries.

18. (1) The Licensing Authority shall authorise and supervise organ exchange with third countries. For this purpose, the Licensing Authority may authorise procurement organisations and transplant centres to conclude agreements with counterparts in third countries.

(2) The supervision of organ exchange with third countries may be delegated by the Licensing Authority to European organ exchange organisations.

(3) European organ exchange organisations may conclude

agreements with counterparts in third countries.

(4) Organ exchange, as referred to in sub-regulation (1), shall be allowed only where the organs:

- (a) can be traced from the donor to the recipient and vice versa;
- (b) meet quality and safety requirements equivalent to those laid down in these regulations.

19. The Licensing Authority may authorise procurement organisations and transplant centres to conclude agreements with European organ exchange organisations, provided that such organisations ensure compliance with the requirements laid down in these regulations, delegating to those organisations, *inter alia*:

European organ
exchange
organisations.

- (a) the performance of activities provided for under the framework for quality and safety;
- (b) specific tasks in relation to the exchanges of organs to and from Member States and third countries.

20. (1) Any person who fails to comply with any of the provisions of these regulations or rules made thereunder, shall be guilty of an offence and shall, on conviction, be liable a fine (*multa*) not exceeding eleven thousand six hundred and forty-six euro (€11,646).

Penalties.

(2) (a) Notwithstanding any other law providing for the trial of offences, where the Authority believes that a person has committed an offence against these regulations, the Licensing Authority shall give notice in writing to such person describing the offence of which the person is accused, indicating the steps to be taken to remedy the offence and the penalty he is required to pay in respect of that offence.

(b) The Minister may further prescribe the penalties that may be demanded by the Licensing Authority in relation to any specified offence provided that such penalty shall not exceed the amount of eleven thousand six hundred and forty-six euro (€11,646).

(3) Where a notice under this article has been given, the person named in the notice may, within twenty-one days of the service of the notice, accept responsibility for the offence specified in the notice and within the same period pay the penalty indicated in the notice, and comply with the relative provision of these regulations or rules made thereunder and no further proceedings may be taken under

Special
procedure.

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this Act in respect of such offence.

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(4) Where the person to whom notice is given under sub-regulation (1) has not paid the penalty within the twenty-one day period referred to in sub-regulation (3) and has not, within the time specified, complied with the requirements of these regulations, criminal proceedings may be taken against him in accordance with the provisions of the Criminal Code, of these regulations and of any other law applicable to the offence.

SCHEDULE**ORGAN AND DONOR CHARACTERISATION****PART A****Minimum data set**

Minimum data - information for the characterisation of organs and donors, which has to be collected for each donation in accordance with regulation 7(1)(b) and without prejudice to regulation 7(2).

Minimum data set

The establishment where the procurement takes place and other general data

Type of donor

Blood group

Gender

Cause of death

Date of death

Date of birth or estimated age

Weight

Height

Past or present history of IV drug abuse

Past or present history of malignant neoplasia

Present history of other transmissible disease

HIV; HCV; HBV tests

Basic information to evaluate the function of the donated organ

PART B**Complementary data set**

Complementary data - information for the characterisation of organs and donors to be collected in addition to minimum data specified in Part A, based on the decision of the medical team, taking into account the availability of such

information and the particular circumstances of the case, in accordance with regulation 7(1)(b).

Complementary data set

General data

Contact details of the procurement organisation/the establishment where the procurement takes place necessary for coordination, allocation and traceability of the organs from donors to recipients and vice versa.

Donor data

Demographic and anthropometrical data required in order to guarantee an appropriate matching between the donor/organ and the recipient.

Donor medical history

Medical history of the donor, in particular the conditions which might affect the suitability of the organs for transplantation and imply the risk of disease transmission.

Physical and clinical data

Data from clinical examination which are necessary for the evaluation of the physiological maintenance of the potential donor as well as any finding revealing conditions which remained undetected during the examination of the donor's medical history and which might affect the suitability of organs for transplantation or might imply the risk of disease transmission.

Laboratory parameters

Data needed for the assessment of the functional characterisation of the organs and for the detection of potentially transmissible diseases and of possible contraindications with respect to organ donation.

Image tests

Image explorations necessary for the assessment of the anatomical status of the organs for transplantation.

Therapy

Treatments administered to the donor and relevant for the assessment of the functional status of the organs and the suitability for organ donation, in particular the use of antibiotics, inotropic support or transfusion therapy.

