

MINISTRY OF HEALTH

**Decree-Law no. 244/94
of 26 September**

In the establishment of the new regime for donation of human organs or tissues for diagnosis or therapeutic purposes, Law no. 12/93, of 22 April, expressly foresaw

the existence of a National Register of Non-Donors, and the issue of an individual non-donor card.

It is therefore necessary to regulate these mechanisms, in order to make it viable to exercise an effective right of opposition to organ donations, that guarantees and provides consistency to the primacy of the individual conscience and intentions on this matter.

Given that this is a procedurally dependent right, there is an urgent need to institutionalise mechanisms which, by means of their simplicity and effectiveness, are available to all those persons who, as a result of their convictions, are not willing to make a post-mortem donation of organs or tissues.

Given the difficulties in generating proof that may arise from consultations of the National Register of Non-Donors, the obligation for registering and archiving such consultations is hereby established, together with the respective details, for a specific time period.

The National Personal Data Protection Commission (CNPDP) was consulted on this matter.

Hence:

Pursuant to the legal regime established by Law no. 12/93, of 22 April, and under the terms of paragraphs a) and c) of no. 1 of article 201 of the Constitution, the Government hereby decrees the following:

Article 1

Object

The present diploma aims to regulate the organization and operation of the National Register of Non-Donors (RENDA) and issue of the respective individual card.

Article 2

Statement of non-availability for donation

1 — Total or partial non-availability for post mortem donation of certain organs or tissues or for assignment of such organs or tissues for certain purposes must be stated to the Ministry of Health, via registration in the RENDA, by filling in a standard printed form, in triplicate, by the respective holders or legal representatives.

2 — The draft version of the standard printed form specified in the previous number shall be approved by a ministerial order from the Minister of Health.

Article 3

Registration in the RENDA

1 — Registration in the RENDA is carried out through presentation of the printed form specified in the previous article, by the interested party or his respective representative, in any health centre or extension.

2 — Filling in the printed form shall be controlled, at the time of its presentation, by the officer receiving the form, by comparing the details of the ID declarations specified within the printed form and those of the ID document proving the holder's identity or right.

3 — Reception of the printed form will be confirmed by immediately delivery of a copy that confirms that the form has been submitted to the competent services, in a legible manner, by the responsible officer or agent who will immediately carry out all the necessary processes to ensure automatic processing of the form in the RENDA.

4 — Registration in the RENDA shall produce its effects four working days after reception of the printed form.

Article 4

Purpose of the file

The purpose of the automated file within the RENDA is to organise and keep updated information related to non-availability for procurement of organs or tissues, for national citizens, stateless persons and foreigners resident in Portugal.

Article 5

Collected data and means of retrieval

1 — The personal data collected for automated processing, related to all citizens registered in the RENDA, under the terms of this diploma, corresponds to the name, address, place of birth and nationality, date of birth, sex, number and date of the ID card or birth certificate, and the organs, tissues or purposes that may not be subject to donation.

2 — Any alteration to the non-availability for donation, together with updating and retrieval of the data specified in the previous number, shall be made by filling in the printed form specified in article 2, by the holders or their legal representatives.

Article 6

Purpose of the data

The personal data specified within the automated file is intended for verification by the entities that, under the terms of applicable legislation will carry out post mortem procurement of tissues or organs, of the existence of any opposition or restrictions to organ donation, prior to commencing such procurement.

Article 7

Communication of the data

1 — Histocompatibility centres, Organ Procurement and Transplantation Coordination Offices and legal medicine institutes are guaranteed uninterrupted connection to the RENDA's computing system for the purposes of consultation of the data specified in article 5.

2 — In the event that it is not possible to carry out a consultation under the terms of the previous number, the data specified in article 5 may be communicated to the specified entities by fax.

Article 8

Security of the information

The officer responsible for the automated file and the entities authorised to access the file, under the terms of the previous article, will adopt the necessary technical measures in order to guarantee that the information cannot be unduly accessed or used for purposes other than that consecrated in this diploma.

Article 9

Conservation of the data

The personal data will be kept for 10 years after the death of the registration holder.

Article 10

Right to the information and access to the data*

1 — Any person is entitled to learn the contents of the registration or records of the automated file of the RENNDA held in his name.

2 — Without prejudice to the conditions that are set under the terms of paragraph j) of no. 1 of article 8 of the Law no. 10/91, of 29 April, the exact reproduction of the records specified in the previous number, with indication of the meaning of any codes and abbreviations held therein, shall be supplied free of charge at the request of the respective holders or legal representatives.

Article 11

Correction of any inaccuracies

Any person shall be entitled to demand correction of any inaccuracies, suppression of unduly registered data and rectification of any omissions, under the terms specified in articles 30 and 31 of Law no. 10/91, of 29 April.

Article 12

Responsible entity

The responsible entity of the automated file of the RENNDA is the Institute of Financial and Computing Management of the Health Service.

Article 13

Confidentiality

1 — Anyone who, through exercise of their professional duties, becomes familiar with the personal data specified within the RENNDA shall be obliged to uphold professional secrecy, even after terminating the respective duties.

2 — Breach of the right specified in the previous number constitutes a disciplinary and civil illicit act.

Article 14

Issue of the card

1 — All citizens who have registered in the RENNDA, under the terms of this diploma, will be supplied with an individual non-donor card, in conformity with a standard format approved by a ministerial order from the Minister of Health.

2 — The Institute of Financial and Computing Management of the Health Service will issue and send the individual non-donor card to the addressee within a maximum of 30 days, counted from the date of reception of the printed form specifying opposition to organ donation.

3 — The card shall contain the identification details of the respective holder.

4 — In the event that the non-availability of organ donation is restricted to certain organs or tissues such restrictions must be specified within the card.

Article 15

Consultation of the RENNDA

1 — Public or private hospital establishments that, under the terms of applicable legislation, carry out post mortem procurement of tissues or organs must, before commencing such procurement, verify, via the Organ Procurement and Transplantation Coordination Offices and the histocompatibility centres, the existence of any opposition or restrictions to the donation specified within the RENNDA.

2 — For purposes of the provisions established in the previous number, the Organ Procurement and Transplantation Coordination Offices and the histocompatibility centres will have a direct connection to the automated file of the RENNDA.

3 — Procurement of tissues by legal medicine institutes, under the terms of applicable law, can only be carried out after verification that there is no opposition thereof, by consulting the RENNDA.

Article 16

Opposition

Without prejudice to the provisions established in the previous article, opposition to the donation may be proven by the copy specified in no. 3 of article 3 or by the non donor card, provided that these are exhibited or found within the possessions of deceased person, prior to commencing the procurement.

Article 17

Certification of consultation of the RENNDA

Consultations of the RENNDA computing system will be registered in a magnetic format under terms that make it possible to prove that the consultation was carried out, together with the respective details.

Checked and approved in the Council of Ministers of 14 July of 1994. — Aníbal António Cavaco Silva — Álvaro José Brilhante Laborinho Lúcio — Adalberto Paulo da Fonseca Mendo — Luís Manuel Gonçalves Marques Mendes.

Proclaimed on 16 August 1994.

Let this be published.

President of the Republic, Mário Soares.

Counter-signed on 22 August 1994.

Prime-Minister, Aníbal António Cavaco Silva.