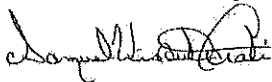


HUMAN BODIES, ORGANS, AND TISSUES  
DONATION & DISPOSAL BOARD OF PUERTO RICO  
SUSCRIPT TO THE  
UNIVERSITY OF PUERTO RICO  
MEDICAL SCIENCES CAMPUS

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HUMAN BODIES, ORGANS, AND TISSUES  
DONATION AND DISPOSAL REGULATION



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## INDEX

<b>DECLARATION OF PRINCIPLES.....</b>	<b>- 3 -</b>
<b>CHAPTER I – GENERAL PROVISIONS.....</b>	<b>- 4 -</b>
Section 1 – Title .....	- 4 -
Section 2 – Legal Basis .....	- 4 -
Section 3 – Purpose .....	- 4 -
Section 4 – Definitions .....	- 4 -
<b>CHAPTER II – POWERS AND DUTIES OF THE BOARD.....</b>	<b>- 8 -</b>
Section 5 – Regulate.....	- 8 -
Section 6 – Storage and Use.....	- 8 -
Section 7 – Registry of Donations.....	- 8 -
Section 8 – Donations to Specific Persons .....	- 9 -
Section 9 – Procurement Organizations .....	- 9 -
Section 10 – Administration.....	- 9 -
Section 11 – Compilation of Reports .....	- 9 -
Section 12 – Operational Mechanisms .....	- 9 -
Section 13 – Agreements.....	- 10 -
Section 14 – Acceptance .....	- 10 -
Section 15 – Cooperation Agreements .....	- 10 -
Section 16 – Professional Services.....	- 10 -
Section 17 – Operational Directives.....	- 11 -
Section 18 – Education Program .....	- 11 -
Section 19 – Report Preparation.....	- 12 -
<b>CHAPTER III – DONORS, DONEES AND DONATION PROCESS .....</b>	<b>- 13 -</b>
Section 20 – Donors .....	- 13 -
Section 21 – Donees .....	- 15 -
Section 22 – Procedure to Become a Donor.....	- 16 -
Section 23 – Autopsies and Removal of Organs and Tissues .....	- 17 -
Section 24 – Compensation.....	- 18 -
Section 25 – Bodies – Medical Examination .....	- 18 -
Section 26 – Notice of Death .....	- 18 -
Section 27 – Specific Donee – Autopsy .....	- 19 -
Section 28 – Acceptance .....	- 19 -
Section 29 – Unclaimed Bodies .....	- 19 -
Section 30 – Transfer to the Medical Sciences Campus.....	- 20 -
Section 31 – Notice to the Demographic Registrar Office .....	- 20 -
Section 32 – Claim .....	- 21 -
Section 33 – Burial or Cremation of the Body .....	- 21 -
Section 34 – Use.....	- 21 -
Section 35 – Revocation of Anatomical Donation .....	- 21 -
<b>CHAPTER IV – PROCEDURE FOR THE USE OF BODIES IN CLINICAL RESEARCH AND TEACHING.....</b>	<b>- 23 -</b>
Section 36 – Registry .....	- 23 -
Section 37 – Academic and Licensed Institutions.....	- 23 -
Section 38 – Distribution of Bodies .....	- 23 -
Section 39 – Identification and Use of Bodies .....	- 23 -
Section 40 – Use in Other Institutions.....	- 24 -
Section 41 – Return of Bodies for Cremation or Burial.....	- 25 -

<b>CHAPTER V – CERTIFICATION GRANTED BY ORGAN, TISSUE AND SKIN PROCUREMENT ORGANIZATIONS .....</b>	<b>- 26 -</b>
Section 42 – Legal Authority .....	- 26 -
Section 43 – Process for Requesting Certification .....	- 26 -
Section 44 – Certification Issued by the Board to Organ Procurement Entities.....	- 27 -
Section 45 – Organ Procurement Entities’ Obligation to Perform Screening Tests on Organ Donors. -	27 -
Section 46 – Denial, Suspension or Revocation of Certification .....	- 27 -
<b>CHAPTER VI – HOSPITAL PROTOCOL FOR THE PROCUREMENT OF ORGANS AND TISSUES .....</b>	<b>- 29 -</b>
Section 47 – Hospital Donor Protocol.....	- 29 -
Section 48 – Institutional Policy on Donations .....	- 29 -
Section 49 – Medical Supervision of Coordinators in the Procurement of Tissues and Organs .....	- 30 -
Section 50 – Organ Procurement for Transplantation by Physicians Licensed in the United States.....	- 30 -
Section 51 – Medical Certification of Death.....	- 31 -
Section 52 – Guidelines for Declaring Brain Death .....	- 31 -
Section 53 – Declaration of Brain Death.....	- 32 -
Section 54 – Autopsy or Removal of Donated Organs - Term.....	- 32 -
<b>CHAPTER VII – SPECIAL PROVISIONS .....</b>	<b>- 33 -</b>
Section 55 – Supervision of Donations .....	- 33 -
Section 56 – Power to Request Reports .....	- 33 -
Section 57 – Obligation to Submit Reports.....	- 33 -
Section 58 – Annual Report .....	- 34 -
Section 59 – Penalties .....	- 34 -
Section 60 – Conflict of Interests .....	- 34 -
Section 61 – Severability.....	- 35 -
Section 62 – Repeal.....	- 35 -
Section 63 – Effectiveness .....	- 35 -
<b>ANNEX I - .....</b>	<b>-38-</b>

# **HUMAN BODIES, ORGANS, AND TISSUES DONATION & DISPOSAL BOARD OF PUERTO RICO**

## **DECLARATION OF PRINCIPLES**

Act No. 34 was adopted on March 30, 1950. This legislation created the Normal Anatomy Board, the purpose of which was to obtain human body donations for practical laboratory work in the first higher education center in Puerto Rico dedicated to the teaching of medicine: School of Tropical Medicine of the University of Puerto Rico.

Science development promoted legislation that resulted in the adoption of Act 11 of April 15, 1974. This Act included the donation of human organs and tissues for transplantation to improve the quality of life of our citizens and expanded the mission and function of the Board.

Today, the Human Bodies, Organs, and Tissues Disposal Board is an entity attached or subscript to the University of Puerto Rico Medical Sciences Campus, created by Act No. 296-2002, as amended, known as the Anatomical Donation Act of Puerto Rico, which expands the Board's composition and reaffirms the original purpose of the previous laws. It does so by promoting the donation of organs and tissues for transplantation and the donation of human bodies for the advancement of science.

Total or partial donation of the body may only be accepted for clinical autopsies or for the purpose of aiding research progress and the teaching of medical sciences and associated standards, in compliance with the rules laid down in this regulation.

Living organ donation may only be accepted for the transplantation or rehabilitation of diseased human body parts or tissues, in compliance with the rules laid down in this regulation.

## **CHAPTER I - GENERAL PROVISIONS**

### **Section 1 - Title**

This regulation will be known and may be cited as “Human Bodies, Organs, and Tissues Donation and Disposal Regulation.”

### **Section 2 - Legal Basis, Act No. 38-2017, as amended, known as the “Government of Puerto Rico Uniform Administrative Procedure Act”**

This regulation is approved under the authority granted to the Human Bodies, Organs, and Tissues Disposal Board, by Section 23 of Act 296-2002, as amended, and by Act No. 38-2017, known as the “Uniform Administrative Procedure Act.”

### **Section 3 - Purpose**

The purpose of this regulation is to establish the rules for the total or partial donation of human bodies, that is, living organs to specific recipients and obtain bodies to be used by schools of medicine in Puerto Rico.

### **Section 4 - Definitions**

The terms listed herein shall have the meaning stated below:

“**Eye Bank**” means the “Banco de Ojos del Leonismo Puertorriqueño” and any other similar entity that may be established in the future in Puerto Rico.

**"Blood Bank"** means any center to collect, process and preserve blood obtained from human beings for the purpose of having it available for use at any time necessary.

**"Cornea"** means the transparent membrane on the surface of the eye that measures approximately 12 mm x 12 mm (millimeters).

**"Donor"** means any person who makes a total or partial donation of his/her body, or that having due legal authorization donates the body of another person.

**"Donee"** means any institution, person or entity authorized by law that has been named beneficiary of the donation.

**"Procurement entity"** means a legal person duly authorized to procure and receive in Puerto Rico donations of organs, tissues or parts of the human body for transplants, such as, but not limited to: blood banks, the Organ Procurement Organization, "Banco de Ojos del Leonismo Puertorriqueño", bone banks, transplant programs or other entities of similar nature, as determined by the Board.

**"School of Medicine"** means every school of medicine duly accredited and authorized as such, pursuant to the laws of the Government of Puerto Rico.

**“School of Dentistry”** means every school of dentistry duly accredited and authorized as such, pursuant to the laws of the Government of Puerto Rico.

**“State”** means the Government of Puerto Rico.

**“Deceased”** means a dead person, including stillborns and fetuses.

**“Hospital”** means a hospital that is authorized, accredited or approved under the laws of the Government of Puerto Rico or of the United States of America.

**“Board”** means the Human Bodies, Organs and Tissues Disposal Board (HBOTDB).

**“Act”** means Act No. 296, approved on December 25, 2002, as amended.

**“Physician”** means a person licensed or otherwise authorized to practice medicine pursuant to the laws of the Government of Puerto Rico, that is part of the medical teams recognized by the *United Network for Organ Sharing*.

**“Death”** means the irreversible cessation of the person’s respiratory and circulatory functions, or the total and irreversible cessation of the person’s brain functions, including those of the brain stem.

**“Organ Procurement Organization, or “OPO”** means the entity authorized and certified by the Federal Government of the United States to procure organs in Puerto Rico.

**“Part”** means any organ or part of the human body, such as the cornea, bones, arteries, blood or other fluids.

**“Person”** means any natural or legal person, or any government instrumentality or agency or its subdivisions.

**“Recipient”** means the person who receives the transplant.

**“United Network for Organ Sharing, or UNOS”** means the entity contracted by the Federal Government of the United States pursuant to the National Organ Transplant Act, which is responsible for maintaining and operating the national computerized registry of persons waiting for an organ transplant and for coordinating the distribution and placement of procured organs in the United States and Puerto Rico.



## **CHAPTER II - POWERS AND DUTIES OF THE BOARD**

The Board shall have the following powers and duties:

### **Section 5 - Regulate**

The Board will adopt those rules and regulations necessary for its internal operation and for the processing of received donations, pursuant to the provisions of the Act.

### **Section 6 - Storage and Use**

The Board will regulate the storage, use and disposal of bodies or parts thereof.

### **Section 7 - Registry of Donations**

The Board will keep a registry in which all donations of bodies or parts thereof made in Puerto Rico shall be registered, pursuant to the provisions of the Act. Each registration will include the name, address and personal circumstances of the donor, as well as the name and address of the donee, nature of the donation, date and place of execution of the donation document and the registration date thereof.

The Board will also create, develop and keep up to date an electronic registry of donors of anatomical donations for transplantation in the manner provided in the Act.

#### **Section 8 - Donation to Specific Persons**

The Board will serve as depository and the entity responsible for the processing of donations in cases in which the donor expresses his/her intention that the donee be a specific person.

#### **Section 9 – Procurement Organizations**

The Board will take into consideration the compliance of organizations responsible for the procurement, processing and distribution of organs and tissues with the rules and procedures established by their regulatory agencies and other organizations that govern them, such as the Food and Drug Administration (FDA).

#### **Section 10 - Administration**

The Board will formulate specific policy for its own operation and administration in accordance with federal and state laws and relevant regulations.

#### **Section 11 - Compilation of Reports**

The Board will require regulated entities to provide the reports, certifications, documents and statistical data that the Board deems necessary to carry out the purposes of the Act.

#### **Section 12 - Operational Mechanisms**

The Board will direct and establish the appropriate mechanisms so that it may carry out its duties as required by the Act.

### **Section 13 – Agreements**

The Board will authorize cooperation agreements, leases, contracts and other agreements necessary for its operation.

### **Section 14 – Acceptance**

The Board will authorize the request, receipt and acceptance of funds, federal or state donations or any other donation in accordance with the applicable regulations.

### **Section 15 – Cooperation Agreements**

The Board will recommend cooperation agreements or agreements made through the Chairperson of the Board with public or private organizations or agencies of the Government of Puerto Rico and the United States or foreign countries, consistent with the public policy established by the Board's Act and any other legal or regulatory provisions of the Government of the Government of Puerto Rico.

### **Section 16 – Professional Services**

The Board will employ the professional services necessary or convenient to advance the purposes of the Act and of the Board's own good and sound public administration, such as healthcare professionals and advertising companies, amongst others.

### **Section 17 – Operational Directives**

The following measures and rulings are adopted to achieve the Operational Direction of the Board:

- a) In the event that a member of the Anatomical Donations Board or his/her representative is absent three or more times from the Board's ordinary meetings, he/she will be asked to be replaced by another representative who is able to attend the meetings as they are scheduled.
- b) The Board may appoint a Vicepresident when it is deemed necessary or advisable, whose main task will be to assist the Chairperson in fulfilling his/her responsibilities, and to substitute when he/she is not available to perform his/her duties for justified reasons.
- c) The Board may pay members mileage expenses whenever they travel to attend ordinary or extraordinary meetings, provided there are funds for such purpose, as stated in Section 2 of Act 296-2002, as amended. Section 2 stipulates that even though the position of member of the Board does not entail compensation, every member will be paid the expenses actually incurred in the performance of his/her duties.

### **Section 18 – Education Program**

The Board will develop a continuous program to educate and inform healthcare professionals, government agencies (namely, all departments, offices, commissions, boards and instrumentalities of the Executive, Legislative or Judicial branches of the Government of Puerto Rico, including public corporations and municipalities), officers, employees and the general public of the meaning and scope of the Act, and of the existing need in Puerto Rico for a greater

number of anatomical donors with the purpose of explaining the benefits, rights and procedures of organ and tissue donations to employees of other agencies.

**Section 19 – Report Preparation**

The Board will prepare reports of its activities and those it promotes and sponsors, including an annual report that is to be submitted to the Governor, the Legislature and the Chancellor's Office of the Medical Sciences Campus.

## CHAPTER III – DONORS, DONEES AND DONATION PROCESS

### Section 20 – Donors

For the purposes of these Regulations, the following may become donors:

- a) Any person eighteen (18) years or older and in full use of his/her mental faculties may donate his/her entire body or any part thereof to the persons, institutions or entities recognized by the Act as authorized recipients for purposes of clinical autopsies, anatomical research or to collaborate with the progress of medical science and associated branches for education, or for the transplantation or rehabilitation of part of the human body or any sick, damaged or degenerated tissues. Such donations will be effective after the death of the donor, except in cases in which the organs or tissues donated are to be transplanted from one living person to another.
- b) For the purposes of the Act, the following persons, in the order specified and excluding any other relative, may dispose of the body of the deceased, in whole or in part:
  - 1. The widow/er or surviving spouse who cohabited with the deceased spouse at the time of his/her death;
  - 2. The eldest child and, in his/her absence or disability, the next eldest in age, provided that he/she is of legal age;
  - 3. The parent with whom the deceased lived;
  - 4. The grandfather or grandmother with whom the deceased lived;
  - 5. The eldest first-degree sibling and, in the absence thereof, the eldest of the half siblings;

6. The guardian of the deceased at the time of death, or the relative or private individual who has cared for the deceased during his/her life;

7. Any person or entity authorized or compelled by law to dispose of the body.

The power of the persons called to authorize the donation may only be exercised in the absence of an express declaration made by the deceased that states his/her intention to donate or not donate their organs or tissues. When the person called to grant authorization is not physically available to do so, he/she may grant authorization to donate organs or tissues by telephone, facsimile or electronic communication, as long as the person can prove his/her identity through those means. In the case of donation of a person's cadaver, the intention to donate may be expressed by telephone, facsimile or electronic communication, but this intention to donate must be then confirmed by presenting the required documentation. The person or entity authorized or obliged by law to dispose of the body of a deceased person may not delegate this function to another person if doing so contravenes the order established in this Section.

c) Any minor of sixteen (16) and seventeen (17) years of age may donate blood in any collecting entity or institution authorized for these purposes by law, with the prior written consent of the father, mother, or legal guardian. In addition, a medical evaluation carried out by the collecting entity or institution authorized for these purposes by law will be required, certifying that the child is eligible to be a blood donor. Nothing herein shall be construed as an exoneration to any blood bank, hospital or other recovery entity, its agents and employees in relation to civil liability for damages caused by obtaining blood from the minor.

The Bureau of Forensic Sciences, hospital or physician in charge of the autopsy or of removing an organ or tissue for transplantation is hereby released of liability if the person that alleges to be authorized to dispose of the body of the deceased, in whole or in part, pursuant to subsection (b) of this Section, subsequently turns out to lack the legal authority to do so.

#### **Section 21 – Donees**

A donation pursuant to the Act may be made in favor of the following donees, but only for the ends and purposes of the Act.

- a) Any hospital, clinic or other medical institution enabled and certified to procure and manage organs and bodies, or any physician or surgeon duly authorized to practice the profession in Puerto Rico.
- b) Any university, college, medical or dental school authorized by the Puerto Rico Council on Education.
- c) Any person effectively appointed by the donor who is in some way associated to any branch of medical science and can prove to the Board that their purpose does not contravene the ends and purposes stated in the Act.
- d) The Human Bodies, Organs and Tissues Disposal Board.
- e) Any institution or entity accredited and certified by the Board to manage, maintain, deposit, remove or carry out processes related to organ or tissue transplantation.



- f) A donation must be notified to the Board within forty-eight (48) hours of its completion.
- g) In the case of a donation of blood by a minor of sixteen (16) and seventeen (17) years, any recovery entity must keep a registry in which it will record the name, age and address of the minor, a description of the document presented by the minor to prove his age, a copy of the medical certificate declaring the minor eligible to donate and a copy of the authorization document to donate blood. The Department of Health of the Government of Puerto Rico is authorized to carry out inspections of the registry book.

#### **Section 22 – Procedure to become a donor**

A person authorized to make an anatomical donation under Article 6 of Act No. 296-2002, as amended, may register his or her intention to become a donor by signing a donor card for organs, tissues, and bodies that meets the requirements set forth below:

- a. Registering electronically in the Donor Registry of Organs, Tissues, and Bodies, in accordance with the provisions of Article 27 of Act No. 296-2002, as amended, or another registry in Puerto Rico or any state of the United States of America that complies with the parameters of Act No. 296-2002, as amended.
- b. Consenting to the donation in their driver's license or identification card, issued by the Department of Transportation and Public Works; or through a private document or donation card, signed before two witnesses, or through a public document sworn before a notary public. The revocation, suspension or cancellation of the driver's license or identification card does not invalidate the donation or the expression of intention to become a donor.

### **Section 23 – Autopsies and Removal of Organs and Tissues**

- a) The pathologist, forensic physician, ophthalmologist, surgeon, or their aids may remove corneas, glands, organs, tissues, or parts from the bodies under the jurisdiction of the Government of Puerto Rico that are subjected to an autopsy by provision of law, to be delivered to the Board for the ends and purposes of this Act, provided that the removal of said corneas, glands, organs or tissues does not interfere with the autopsy or with any investigation being performed by competent authorities, or alters the *post mortem* physical appearance of the body. In the case of corneas, they will be delivered free of charge to the Lions Eye Bank of Puerto Rico or other existing accredited nonprofit eye banks.
- b) In accordance with Act No. 296-2002, as amended, the Bureau of Forensic Sciences, the Board, hospitals, transplanting physicians, the forensic doctors or his/her assistant, the ophthalmologist, the ophthalmology resident, the Eye Bank or its officials are hereby released from civil and criminal liability. The recipient patient of the corneas of a deceased donor is hereby also released from civil and criminal liability if after the removal of the corneas any person alleges that his/her approval or previous knowledge was required.
- c) Every donor of tissues, organs or body or parts thereof, or of a body for clinical autopsy, and every notary before who an anatomical donation document or revocation of donation of a body or part thereof is executed, shall remit a simple copy of said document with his/her signature to the Human Bodies, Organs and Tissues Disposal Board within seventy-two (72) hours after the execution of the document.

#### **Section 24 – Compensation**

Total or partial donations of a body or organs for a living-donor transplantation will not be subject to any compensation or remuneration whatsoever. It will not be construed as a violation to this Section that the donee or any other person pay for the expenses actually incurred in the donation.

#### **Section 25 – Bodies – Medical Examination**

Total or partial donation of a body or organ for a living-donor transplantation entails a physician's authorization to determine if the donated body or part thereof meets the conditions necessary for its intended use.

The rights of the donee that arise from the donation will prevail over those of other persons, subject to those provisions of law pertaining to medical autopsies.

#### **Section 26 – Notice of Death**

Hospitals shall notify the Organ Procurement Organization of all deaths or imminent deaths. Moreover, when the death of a person, whose body or parts thereof are bequeathed or donated for the ends and purposes of the Act, occurs in a hospital, and the hospital is aware of these circumstances, said hospital must immediately notify the Board of the person's death. The Board, in turn, must notify both the donee, if they are a specific person, and the procurement entities that the donor designated as beneficiaries of the donation.

The Board is empowered to provide all that is necessary for the preservation of the body in those cases in which the donee lacks the conditions needed for its preservation.

### **Section 27 – Specific Donee – Autopsy**

The autopsy of a person whose body or part thereof has been bequeathed or donated, pursuant to the ends and purposes of the Act, to a specific donee shall be performed in the hospital where the death occurred. The autopsy expenses will be defrayed by the donee. However, if the hospital lacks the facilities to perform the autopsy, it must notify the Board for the final disposal of the body.

### **Section 28 – Acceptance**

The donee may accept the donation or bequest of a body in its totality, accept only the parts of the deceased's body that he/she deems useful or refuse the donation or bequest in its totality. In the case of partial acceptance or total refusal, he/she will notify the Board within twenty-four (24) hours following the donor's death. In these cases, or if after the twenty-four (24) hour period following the donor's death the donee fails to claim the body, said body may be handed over to the person(s) authorized by law to dispose of it. If these persons, in turn, fail to claim it, the Board must dispose of the body as if the donation had been made in its name.

### **Section 29 – Unclaimed Bodies**

When a person dies in a hospital, psychiatric hospital, public asylum, or any other charitable institution, or public or private healthcare institution or penitentiary, said institution has the duty to notify the death to the Board if the institution does not know who are the family members or caretakers of the deceased. Likewise, in cases in which the person dies and his/her body is not claimed within twenty-four (24) hours after their relatives or caretakers have been duly notified, said institution will have the obligation to notify the death to the Board. The

prosecutors, the Court of First Instance, the Bureau of Forensic Sciences and the Puerto Rico Police Bureau will have the same obligation in cases in which unknown persons die in public places and whose bodies are not claimed by their families or caretakers within twenty-four (24) hours after they have been duly notified.

The Board has the duty to inform these institutions and agencies of the obligations imposed by law and this regulation.

#### **Section 30 – Transfer to the Medical Sciences Campus**

The Board will provide all that is necessary for the immediate transfer of these bodies to the entity designated by the Board for such purposes, and for their preservation for a period of five (5) days. During this period, the Board may not use these bodies in the expectation that any of the relatives previously listed in this Chapter, or any institution of which the deceased was part of, may request its delivery.

#### **Section 31 – Notice to the Demographic Registrar Office**

The Board must notify the Demographic Registrar of the place from where the bodies were removed, as well as their transfer to the University of Puerto Rico Medical Sciences Campus.

### **Section 32 – Claim**

The person or entity that requests the delivery of a body that has been removed and preserved by the Board will have the obligation to notify the Demographic Registrar in advance of their claim of the body. If the petitioners have sufficient financial resources, they shall pay the Board the expenses incurred for the perfusion and transportation of the body.

### **Section 33 – Burial or Cremation of the Body**

Once studies on a body are concluded and no relative has come forward to claim it, the Board will have the power to proceed with the burial or cremation of the body.

### **Section 34 – Use**

- a) The bodies donated to the Board will be used for the purposes established in the donation.
- b) Unclaimed bodies will be used exclusively for the donation of organs and tissues or for anatomical demonstrations, dissection and other similar purposes pertaining to education, health and the progress of medicine.

### **Section 35 – Revocation of Anatomical Donation**

The willingness to donate the body, any of its organs or tissues is a voluntary statement of the citizen which may be withdrawn by the citizen whenever he/she desires to do so.

The notice of revocation of an anatomical donation must be done in writing and be sent by the donor to the Human Bodies, Organs and Tissues Disposal Board. The Board will acknowledge receipt of the notice of revocation of donation in a copy of the written document

submitted by the donor, sending it to the official address of the donor, as it appears in the Board's registry.

## **CHAPTER IV – PROCEDURE FOR THE USE OF BODIES IN CLINICAL RESEARCH AND TEACHING**

### **Section 36 – Registry**

The Board will keep an electronic registry of the bodies that are received and available for academic and clinical research purposes.

### **Section 37 – Academic and Licensed Institutions**

The Board may receive requests for bodies that are used for teaching or medical research in institutions that are duly accredited by the Board of Education or licensed by the Department of Health if it is a healthcare entity. Requests for the use of bodies by individuals who are ascribed to educational or healthcare institutions will be accepted only if the body is used in an entity that is accredited or licensed by an agency of the Government of Puerto Rico.

### **Section 38 – Distribution of Bodies**

Bodies received by the Board will be distributed to the requesting entities according to the needs of each institution and the number of bodies available. Each institution must allocate an amount of money to cover the costs of transportation and preparation of the specimens it receives.

### **Section 39 – Identification and Use of Bodies**

Institutions that receive bodies will keep a record for each body similar to that of the Board, using serial numbers that match those of the Board's registry, and will always properly identify the remains by serial number and not by name. The bodies will not be publicly exposed.



Access to the dissection laboratory will be regulated by the Head of the Department of Anatomy so that it is only available to members of the medical faculty, and persons studying medicine and associated disciplines. Likewise, access to the laboratory will be granted to professors and technical staff of the Department, including auxiliary staff and medical and scientific researchers, only if they have a permit from the Head of the Department of Anatomy. Access to the dissection laboratory in other cases will be determined by the Head of the Department of Anatomy in consultation with the Board's staff. Any other exception is to be made exclusively by the Head of the Department of Anatomy and the Deans of the relevant school. Anatomical material may be removed outside the Department of Anatomy and outside the Medical School only for scientific reasons and with permission of the Head of the Department of Anatomy, in accordance with the current norms established by the Board and with its prior notification.

#### **Section 40 – Use in Other Institutions**

Properly preserved material may be loaned for anatomical demonstrations in other educational organizations and institutions in Puerto Rico, through previous agreements established by the Head of the Department of Anatomy. A member of the Faculty or Board of the Organization will be directly responsible for the care of the loaned material. Once used, the material will be returned to the Board or Institution of Origin. The costs for special preparations (if any) will be paid by the requesting Institution.

The Medical Schools of Puerto Rico may cooperate with other institutions or Medical and Dentistry teaching programs in the United States or foreign countries through resource exchange or preparation arrangements if such exchange is carried out in accordance with the laws of the respective state or country.

#### **Section 41 – Return of Bodies for Cremation or Burial**

After a body has been used for the purposes provided in the Law, the remains will be cremated or buried. In the case of burials, the remains will be placed in a duly identified sealed, individual container. The remains will be buried in the public cemetery of the municipality chosen by the person authorized by law to dispose of the body, provided that the funeral or transportation expenses be defrayed by said authorized person. If the remains are to be cremated, the Institute of Forensic Sciences or applicable government agencies must grant approval. The costs of the cremation will be defrayed by the person authorized by law to dispose of the body, as well as the subsequent disposal of the ashes.

## **CHAPTER V – CERTIFICATION GRANTED BY ORGAN, TISSUE AND SKIN PROCUREMENT ORGANIZATIONS**

### **Section 42 – Legal Authority**

Section 5 of Act No. 296-2002, as amended, authorizes the Board to take into consideration an organ and tissue procurement organization's compliance with the rules and procedures established by their regulating agencies and other organizations that govern them.

### **Section 43 – Process for Requesting Certification**

Any entity authorized by federal law to procure organs and tissues in Puerto Rico, and that is duly authorized and regulated by a federal agency, may obtain a certification issued by the Board to carry out its tasks in the Government of Puerto Rico. The following documents must be submitted for this purpose:

- a) Certification or authorization from the accrediting federal agency.
- b) Copy of the federal Act that authorizes its operations in the Government of Puerto Rico.
- c) Certification issued by the Department of State of Puerto Rico proclaiming that the organization is authorized to conduct business in Puerto Rico.
- d) Employer social security number.
- e) A resolution approved by the organization's Board of Directors authorizing its officials to perform their mission in Puerto Rico and certifying that they will comply with all requirements imposed by the laws and regulations of the Government of Puerto Rico and the rules issued by the Human Bodies, Organs, and Tissues Disposal Board.

**Section 44 – Certification Issued by the Board to Organ Procurement Entities**

Once the organ procurement entities provide the previously described documentation, the Board will issue the certificate, pursuant to Section 7(e) of Act No. 296-2002, as amended.

**Section 45 – Organ Procurement Entities’ Obligation to Perform Screening Tests on Organ Donors**

Organ and tissue procurement entities will be required to perform screening tests on organ donors to determine if they have HIV (AIDS), hepatitis and other diseases that can be transmitted through organ and tissue transplantation.

**Section 46 – Denial, Suspension or Revocation of Certification**

The Board may deny, suspend or revoke the certification of any organ or tissue procurement entity, following prior notification and conclusion of an administrative hearing in accordance with the provisions of Act No. 38-2017, on any of the following grounds:

- a) Does not meet the requirements established in this rulings to obtain certification.
- b) Has dedicated itself to organ and tissue procurement without the proper legal authorization.
- c) Has obtained or tried to obtain certification through deceptive or fraudulent means.
- d) Has participated in organ and tissue procurement activities with an expired certification.
- e) Has incurred in conduct proscribed by law.

- f) Has had a history of complaints adjudicated against it by the Board of Anatomical Donations.
- g) Does not comply with the regulatory requirements of an agency of the Government of Puerto Rico or of the Board of Anatomical Donations.

## **CHAPTER VI – HOSPITAL PROTOCOL FOR THE PROCUREMENT OF ORGANS AND TISSUES**

### **Section 47 – Hospital Donor Protocol**

All hospitals will develop a hospital Donor Protocol to identify donors of bodies, organs and tissues. It will be the duty of the hospital administrator or his/her authorized representative upon notifying the death of a patient to ask the next of kin whether the deceased is an organ donor or if he/she expressed their wish to be an organ donor prior to death. If the deceased did not express his/her intention of being an organ donor, the next of kin will be made aware that they may choose to donate the deceased's entire body, or part thereof, which will be used to extend or improve the quality of life of other persons.

### **Section 48 – Institutional Policy on Donations**

The "Protocol" must contain a description of the institutional policy on donations in its preamble. Said description must clearly establish the hospital's commitment to the creation of an organ and tissue donation program with aims to comply with state and federal laws and regulations, and the applicable Board standards.

The hospital administrator or his/her authorized representative will refrain from requesting a donation when he/she is aware of the deceased's manifest will to not be an organ donor, or is aware of the next of kin's opposition to the donation.

The completion of a hospital Donor Protocol pursuant to this Chapter will be recorded in the deceased's medical record and death certificate.

**Section 49 – Medical Supervision of Coordinators in the Procurement of Tissues and Organs**

Organ procurement organizations, tissue banks and eye banks may employ coordinators who are registered nurses, medical assistants or other personnel trained in the field of medicine who meet the relevant standards for organ procurement organizations, tissue banks and eye banks, as adopted by the Secretary of Health, to assist in the medical administration of organ donors or in the surgical removal of organs, tissues and corneas for research or transplantation. A coordinator who assists in the surgical removal of organs, tissues or eyes for research or transplantation must do so under the direction and supervision of a licensed medical director whose authorization stems from the rules and guidelines adopted by the Secretary of Health. With the exception of organ removal, this supervision may be indirect. For purposes of this section, the term “indirect supervision” means that the medical director is responsible for the medical actions of the coordinator, that the coordinator is operating under protocols expressly approved by the medical director, and that the medical director or his/her designated physician is available, personally or by telephone, to provide medical instruction, consultation or counseling in cases of donations or the removal of organs, tissues and corneas.

**Section 50 – Organ Procurement for Transplantation by Physicians Licensed in the United States**

Any physician who specializes in the practice of obtaining organs for transplantation and who have their license to practice medicine and surgery in the United States up to date may remove organs for transplantation through surgical methods if:

- a) The organs are procured for a patient outside of Puerto Rico who is on, or referred by, the United Network for Organ Sharing System, and
- b) The organs have been procured through the sponsorship of an organization certified in Puerto Rico for organ procurement.

#### **Section 51 – Medical Certification of Death**

When a body's organs are used for transplantation, the certification of death, issued by two (2) physicians authorized to practice medicine in Puerto Rico, will be conclusive. With the exception of the removal of corneas, the physicians who certify the death may neither participate in the autopsy or removal of the tissues or organs, nor in their transplantation. Nevertheless, they may be present during the above-stated procedures to provide information regarding the condition his/her former patient.

Brain death will be determined pursuant to the criteria established in the guidelines issued by the Human Bodies, Organs and Tissues Disposal Board.

#### **Section 52 – Guidelines for Declaring Brain Death**

The Board will issue guidelines for the declaration of brain death, which shall be used in all hospital or medical entities located in the Government of Puerto Rico whose physicians are required to participate in the process of declaring brain death (see Annex 1).



**Section 53 – Declaration of Brain Death**

Any declaration of brain death made pursuant to the guidelines issued by the Board as described in Annex 1 of this regulation meets the “death” definition established in Act No. 296-2002, as amended.

**Section 54 – Autopsy or Removal of Donated Organs – Term**

The Board or any organ and tissue procurement organization will have up to seventy-two (72) hours, starting from the time of death, to perform the autopsy or to remove any organ, tissue or part of the body donated to the Board or the organization, or to any specific donee. Neither the Board nor any organ and tissue procurement organization will be civilly or criminally liable for the use of bodies, clinical autopsy or removal of organs, tissues or parts of the body unless it has been notified of the revocation of the bequest or donation, or the annulment of the document that authorized the procedure, or has acted in contravention of the provisions of the donation document.

If the autopsy is performed in the same hospital where the death occurred, a copy of the autopsy protocol must be sent to the Board for filing.

## **CHAPTER VII – SPECIAL PROVISIONS**

### **Section 55 – Supervision of Donations**

The Board of Anatomical Donations, which was created by virtue of Act No. 296-2002, as amended, is hereby empowered to supervise the donation of organs, tissues and bodies in Puerto Rico, in accordance with the provisions of the Law and powers granted thereto by this regulation. The Board may:

- a) Investigate the regulated entities, and
- b) Impose sanctions for violations to this regulation.

### **Section 56 – Power to Request Reports**

The Board will have the power to request information and statistics from any organization or person that participates in the process of donation or procurement of human bodies, organs or tissues in the Government of Puerto Rico. This includes Medical Schools and Human organs and tissues procurement organizations.

### **Section 57 – Obligation to Submit Reports**

The entity or person to whom information on donations or procurement of human organs and tissues has been requested will have the obligation to render the required reports within the terms established by the Board.

### **Section 58 – Annual Report**

The Board will publish an annual report outlining its work and the work of the entities that participate in the processes of donation and procurement of human organs and tissues in Puerto Rico, including statistics of donations obtained and transplants accomplished throughout the year. The report will be submitted to the Chancellor's Office of the Medical Sciences Campus, the Legislature and the Governor of Puerto Rico.

### **Section 59 – Penalties**

Any violation to this Regulation will be evaluated under the provisions of Act No. 97 of June 25, 1962, as amended, known as "Clinical Analysis Laboratories, Plasmapheresis Centers, Seropheresis Centers, and Blood Banks Act," 24 L.P.R.A. §§ 91 et. seq., and Act No. 296-2002, as amended. The Board is hereby empowered to impose administrative fines for any violation to this Regulation, in accordance with the provisions of Act No. 38-2017, known as the "Uniform Administrative Procedure Act" of the Government of Puerto Rico.

### **Section 60 – Conflict of Interests**

Under no circumstances will Board members, or their officers and employees, participate in conflicting activities on behalf of or in representation of the Board if said Board members, officers and employees could be affected by personal interests motivated by ties of consanguinity or affinity, gratification and/or to obtain economic interests.

### **Section 61 – Severability**

If any section or part of this Regulation is found unconstitutional by a court of competent jurisdiction, said judgment will not invalidate the remaining provisions.

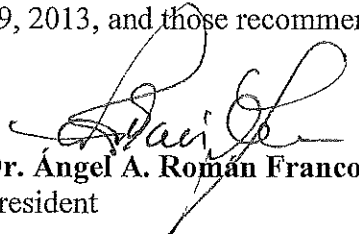
### **Section 62 – Repeal**

This Regulation repeals the Donation and Disposal of Human Bodies, Organs and Tissues Regulation, Regulation No. 7297, Human Bodies, Organs and Tissues Disposal Board (February 20, 2007), as well as any other regulation, rule, administrative order, circular letter, memorandum, written communication or previous instruction that contravenes this Regulation.


### **Section 63 – Effectiveness**

This Regulation will be effective thirty (30) days after having been filed at the Department of State of Puerto Rico.


Ratification today, April 10, 2019, of the amendments to the Regulations of the Board of Anatomical Donations, originally approved in an extraordinary meeting in San Juan, on January 29, 2013, and those recommended by the Department of Justice through letter of July 26, 2018.



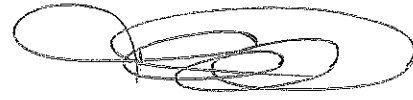
**Dr. Ángel A. Román Franco**  
President



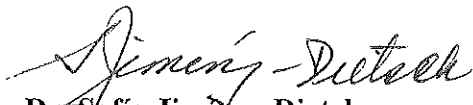
**Dr. Jaime Inserni**  
Neurosurgeon




**Dr. Nivia Pérez Acevedo**  
Dept. Anatomy & Neurobiology – UPR MSC



**Leda. Raquel Núñez Alicea**  
Representative of the Community



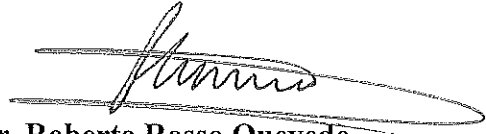
**Dr. Sofia Jiménez Dietch**  
Universidad Central del Caribe




**Héctor J. Figueroa Ramos**  
Forensic Sciences Bureau



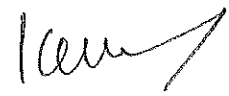
**Dr. Jorge Pérez**  
San Juan Bautista School of Medicine



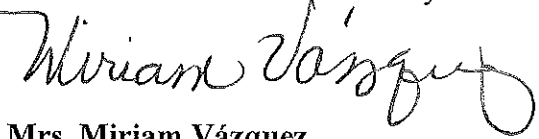
**Dr. Roberto Rosso Quevedo**  
Representative of the Health Secretary




**Lcdo. David Rodríguez**  
Ponce Health Sciences University



**Lcda. Ileana Espada**  
Representative of the Justice Secretary



**Mrs. Miriam Vázquez**  
Banco de Ojos del Leonismo Puertorriqueño



**Mr. Antonio De Vera**  
LifeLink de PR

## **ANNEX 1**

GUIDELINES FOR ESTABLISHING A PROTOCOL FOR THE DECLARATION OF  
BRAIN DEATH IN PUERTO RICO

ACT NO. 296 OF DECEMBER 25, 2002  
SECTION 52 OF THE GENERAL REGULATION OF THE HUMAN BODIES, ORGANS,  
AND TISSUES DISPOSAL BOARD

Approved on September 15, 2006  
San Juan, Puerto Rico

**Purpose:**

To establish guidelines for determining the death of a patient when respiratory and circulatory functions are being supported by artificial means.

**CRITERIA FOR DETERMINING BRAIN DEATH IN ADULTS AND CHILDREN**

Criteria for the Clinical Diagnosis of Brain Death

- A. Pre-requisites: brain death means the absence of all clinical functions of the brain when the immediate cause is known and its irreversibility is demonstrated.
- 1) Catastrophic events that affect both cerebral hemispheres and the brain stem.
  - 2) Clinical and neuroimaging evidence of an acute Central Nervous System catastrophe that is consistent with the diagnosis of Brain Death.
  - 3) Exclusion of medical conditions that may confound the clinical diagnosis (e.g. severe electrolytic, acid-base, endocrine or hypothermic disturbances).
  - 4) Absence of intoxication by drugs, poison or the presence paralyzing agents, as well as other medication that can weaken brain function.
  - 5) Central temperature 32 °C or higher.
- B. The three main indicators of brain death are: coma, absence of brain stem reflexes, and apnea.
- 1) Coma or absence of motor response: when applying a painful stimulus in the supraorbital region, nails or temporomandibular joints.
  - 2) Absence of brain stem reflexes.



- a. Examination of the pupils:
  - I. Absence of response to bright light.
  - II. Pupil dilatation from 4 to 9 mm.
- b. Eye movement:
  - I. Absence of oculoccephalic reflex (test is performed only when the cervical spine is devoid of fractures or instability).
  - II. Oculovestibular reflex - Procedure: The head is elevated to 30° and the ear is examined for serous obstruction. Then, 50-100 cc of iced water is instilled in each ear. The waiting period for responsiveness is 1 minute, and at least 5 minutes to carry out the procedure in each ear.
- c. Facial sensation and motor response:
  - I. Absence of corneal reflexes.
  - II. Absence of mandibular reflex.
  - III. Absence of response to pain stimulus.
- d. Tracheal and pharyngeal reflexes:
  - I. No response after stimulation to posterior pharynx.
  - II. No response to cough stimulus or presence of bradyarrhythmia after bronchial suction.

3) Apnea Test:

- a. Systolic pressure  $\geq 90$  mm Hg.
- b. Pre-oxygenate with 100% O<sub>2</sub> for 10 minutes.

- c. Perform arterial gas test to obtain CO<sub>2</sub> within normal parameters.
- d. Disconnect the ventilator, administer O<sub>2</sub> at 8-12 L/min per tracheal cannula.
- e. Look for spontaneous (tidal) breathing.
- f. After 7 minutes, extract arterial gases. It is necessary that the PCO<sub>2</sub>  $\geq$  60 mm Hg or an increase of  $\geq$  20 mm Hg over the initial results. Another alternative is the administration of exogenous CO<sub>2</sub> to shorten the waiting period.
- g. If spontaneous ventilation occurs, the patient is not in apnea and, therefore, does not meet this diagnostic criterion for brain death.
- h. If hypotension or arrhythmia develops, the patient must be connected immediately to the ventilator. The test must be repeated within 30 minutes.
- i. If the test is negative, consider additional confirmatory tests other than an EEG.

4) The following manifestations may occasionally be observed and should not be confused as evidence of brain stem function:

- a. Spontaneous spinal movements.
- b. Respiratory-like movements.
- c. Sweating, tachycardia and redness.
- d. Normal blood pressure without the use of medications.
- e. Absence of Diabetes Insipidus.
- f. Deep tendon reflexes.

- g. Babinski reflexes.
- h. Movement of the toes.

5) Brain death is a clinical diagnosis. Confirmatory tests are not mandatory unless required by the physician, except in the following cases:

- a. Hypothermia ( $< 32^{\circ}\text{C}$ ).
- b. Drug intoxication.
- c. Severe metabolic imbalance (except hyponatremia).
- d. Unknown medical history.
- e. Neurological examination cannot be performed for physical reasons (severe head and facial trauma).
- f. Children, newborns and infants.

6) Documentation in the medical record:

- a. Etiology and cerebral irreversibility.
- b. Absence of brain stem reflex.
- c. Absence of motor response to pain.
- d. Absence of breaths with  $\text{PCO}_2 \geq 60 \text{ mm Hg}$  or 20 mm Hg above normal levels.
- e. Rationale for the performance, or lack thereof, of confirmatory tests.

7) Determination of brain death in pediatric patients:

- a. Standardized apnea test (may be done after meeting the other criteria).
- b. The patient should not be hypothermic below 36.5 °C or hypotensive, in accordance to his/her age.
- c. Test results should remain consistent with brain death across all observations.
- d. Recommended observation time periods following brain death depend on the age of the patient and the laboratory tests performed:

I. 7 days to 2 months:

Two evaluations and two isoelectric EEGs at forty-eight (48) hour intervals. Consider testing for cerebral blood flow.

II. 2 months to one year:

Two evaluations and two isoelectric EEGs at twenty-four (24) hour intervals. It will not be necessary to repeat the clinical examination and EEG if the cerebral blood flow test, such as cerebral angiography or nuclear medicine perfusion test, shows absence of cerebral flow or does not picture cerebral arteries.

III. Older than one year:

When the irreversible cause of brain damage exists (is known), confirmatory tests are not necessary. Perform two tests or clinical examinations at twelve (12) hour intervals. If confirmatory studies are needed, cerebral blood flow assessment will be used.

## DEATH CRITERIA

1. Act No. 296-2002, as amended, states that when a body's organs are used for transplants, the certification of death, issued by two (2) physicians authorized to practice medicine in Puerto Rico, will be conclusive.
2. The declaration of brain death will be made by two physicians with permanent licenses issued by the Government of Puerto Rico, qualified to determine brain death.