

Date of Notice: September 12, 2017

STATE OF RHODE ISLAND DEPARTMENT OF HEALTH PUBLIC NOTICE OF PROPOSED RULE MAKING

In accordance with Rhode Island General Laws (RIGL) 23-17-10, notice is hereby given that the Rhode Island Department of Health (RIDOH) proposes to repeal the following rule: Rules and Regulations Pertaining to Procurement of Anatomical Gifts (R23-18.6.1-ANAT). The proposed repeal would supersede ERLID 4950 (Effective January 7, 2008).

REGULATION TITLE:

Rules and Regulations Pertaining to Procurement of Anatomical Gifts [R23-18.6.1-ANAT]

TYPE OF FILING: Repeal

RULEMAKING ACTION: Public Notice of Proposed Rule Making

TIMETABLE FOR ACTION ON THE PROPOSED RULE: The public comment period ends on Friday, October 13, 2017.

SUMMARY OF PROPOSED RULE: The RIDOH is proposing a repeal of this rule as it contains identical language to the statute and is therefore redundant.

COMMENTS INVITED: All interested parties are invite to submit written comments concerning the proposed regulations. Written comments can be submitted by mail to Paula Pullano, Rhode Island Department of Health, 3 Capitol Hill, Providence, RI 02908-5097 or by email at paula.pullano@health.ri.gov by the close of **Friday, October 13, 2017**. Please note that comments submitted to RIDOH by other means than the prescribed mailing and email address may not be received and addressed in RIDOH's concise explanatory statement. To ensure that your comments are received, please send them to the prescribed mailing and email address.

WHERE COMMENTS MAY BE INSPECTED: Rhode Island Department of Health, 3 Capitol Hill, Providence, Rhode Island 02908-5097.

FOR FURTHER INFORMATION CONTACT: Paula Pullano, Rhode Island Department of Health, Division of Policy, Information, and Communications, 3 Capitol Hill, Providence, Rhode Island 02908-5097, 401-222-1042, paula.pullano@health.ri.gov.

AUTHORITY FOR THE RULEMAKING: Section 23-18.6.1 of the Rhode Island General Laws.

REGULATORY FINDINGS: In its determination to repeal this rule, RIDOH gave consideration

to: 1) alternative approaches; 2) overlap or duplication with other statutory and regulatory provisions; and 3) significant economic impact on small business. Based on the duplication of existing statutory provisions, it was determined that repeal of the rule was the most appropriate course of action.

THE PROPOSED AMENDMENT: RIDOH proposes to repeal the Rules and Regulations Pertaining to Procurement of Anatomical Gifts (R23-18.6.1-ANAT) in its entirety.

STATE OF RHODE ISLAND RHODE ISLAND DEPARTMENT OF HEALTH CONCISE STATEMENT OF PROPOSED NON-TECHNICAL AMENDMENTS (AMENDMENTS TO AN EXISTING REGULATION)

In accordance with the Administrative Procedures Act, Section 42-35-3 (a) (1) of the RIGL, following is a concise statement of proposed non-technical amendments to the Rules and Regulations Pertaining to Procurement of Anatomical Gifts (R23-18.6.1-ANAT). The proposed regulations would supersede ERLID 4950 (Effective January 7, 2008).

Amendment Coordinates	Rationale/Summary of Change
Page #, Section #, and line #	Description of changes, including reason(s) for the change.
Entire regulation	Entire regulation to be repealed.

RULES AND REGULATIONS PERTAINING TO PROCUREMENT OF ANATOMICAL GIFTS

[R23-18.6.1-ANAT]



STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH

December 2007

INTRODUCTION

These Rules and Regulations Pertaining to Procurement of Anatomical Gifts [R23-18.6.1-ANAT] are promulgated pursuant to the authority conferred under Chapter 23-18.6.1 of the General Laws of Rhode Island, as amended, for the purpose of implementing the Revised Uniform Anatomical Gift Act.

Pursuant to the provisions of Section 42-35-3(c) of the General Laws of Rhode Island, as amended, the following were given consideration in arriving at these regulations:

- (1) Alternative approaches to the regulations; and
- (2) Duplication or overlap with other state regulations.

Based on the available information, no known alternative approach, duplication or overlap were identified.

These rules and regulations are new in their entirety. The prior regulations dealing with this subject matter, *Rules and Regulations Relating to Procurement of Anatomical Gifts From Persons With Unknown Intent*, have been repealed due to repeal of their enabling statute [RIGL 23-18.6] pursuant to PL 2007-476. An administrative action to formally repeal these prior regulations has been filed with the Secretary of State, concurrent with the filing of these Regulations.

All references to section numbers shall refer to sections in these Rules and Regulations Pertaining to Procurement of Anatomical Gifts, unless otherwise specified.

TABLE OF CONTENTS

			Page
Secti	ion 1.0	Definitions	1
Secti	ion 2.0	Scope and Applicability	
2.1	Applic	eability	4
2.2	Person	ns Authorized to Receive an Anatomical Gift	4
2.3	Refusal to Make Anatomical Gift		5
2.4	Preclusive Effect of Anatomical Gift, Amendment or Revocation		6
Secti	ion 3.0	General Requirements	
3.1	Search	Search and Notification	
3.2	Docum	nent of Gift – Delivery and Right to Examine	7
3.3	Presur	nption of Validity	7
3.4	Immunity		7
3.5	Organ	Procurement	8
Secti	ion 4.0	Anatomical Cifts Prior to Donor's Death	
4.1	Person	as Authorized to Make Anatomical Gift	8
4.2	Manner of Making Anatomical Gift		8
4.3	Amen	ding or Revoking Anatomical Gift	9
Secti	ion 5.0	Anatomical Gifts of Decedent's Body Or Part	
5.1	Person	as Authorized to Make Anatomical Gift	10
5.2	Manno	er of Making, Amending or Revoking Anatomical Gift	10
Secti	ion 6.0	Hospital, Organ Procurement Organization, Medical Examiner and Donor Registry	
6.1	Coord	ination of Procurement and Use	11
6.2	Rights	and Duties of Procurement Organization and Others.	11
6.3	Coope	Cooperation Between Medical Examiner and Procurement Organization	
6.4	Facilit	Facilitation of Anatomical Gift From Decedent.	
6.5	Donor	Donor Registry	
Secti	on 7.0	Prohibitions and Penalties	
7.1	Sale o	r Purchase of Parts Prohibited.	14
7.2	Other	Prohibited Acts	14
Secti	ion 8.0	Severability	14

Section 1.0 **DEFINITIONS**

Whenever used in these rules and regulations, the following terms shall be construed as follows:

- 1.1 "Act" means Chapter 23-18.6.1 of the Rhode Island General Laws, as amended, entitled "Revised Uniform Anatomical Gift Act."
- 1.2 "Adult" means an individual who is at least eighteen (18) years of age.
- 1.3 "Agent" means an individual:
 - (1) Authorized to make health care decisions on the principal's behalf by a power of attorney for health care; or
 - (2) Expressly authorized to make an anatomical gift on the principal's behalf by any other record signed by the principal.
- 1.4 "Anatomical Gift" means a donation of all or part of a human body to take effect after the donor's death for the purpose of transplantation, therapy, research, or education.
- 1.5 "Decedent" means a deceased individual whose body or part is or may be the source of an anatomical gift. The term includes a stillborn infant and, subject to restrictions imposed by law other than the Act, a fetus.
- 1.6 "Disinterested Witness" means a witness other than the spouse, child, parent, sibling, grandchild, grandparent, or guardian of the individual who makes, amends, revokes, or refuses to make an anatomical gift, or another adult who exhibited special care and concern for the individual. The term does not include a person to which an anatomical gift could pass under Section 2.2 of these Regulations.
- 1.7 "Document of Gift" means inclusion in a donor registry, a donor card or other record used to make an anatomical gift. The term includes a statement or symbol on a driver's license or identification card.
- 1.8 "Donor" means an individual whose body or part is the subject of an anatomical gift.
- 1.9 "Donor Registry" means the Rhode Island Donor Registry established under RIGL 31-10-26.1 as well as any other electronic database that identifies donors and complies with Section 6.5 of these Regulations.
- 1.10 "Driver's License" means a motor vehicle or chauffeurs license or permit issued by the Department of Motor Vehicles, whether or not conditions are attached to the license or permit.
- 1.11 "Eye Bank" means a person that is licensed, accredited, or regulated under federal or state law to engage in the recovery, screening, testing, processing, storage, or distribution of human eyes or portions of human eyes.
- 1.12 "Guardian" means a person appointed by a court to make decisions regarding the support, care, education, health, or welfare of an individual. The term does not include a guardian ad litem.
- 1.13 "Hospital" means a facility licensed as a hospital under the law of any state or a facility operated as a hospital by the United States, a state, or a subdivision of a state.

- 1.14 "Identification Card" means an identification card issued by the Department of Motor Vehicles.
- 1.15 "Know" means to have actual knowledge.
- 1.16 "Minor" means an individual who is under eighteen (18) years of age.
- 1.17 "Organ Procurement Organization" means a person designated by the Secretary of the United States Department of Health and Human Services as an organ procurement organization.
- 1.18 "Parent" means a parent whose parental rights have not been terminated.
- 1.19 "Part" means an organ, an eye, or tissue of a human being. The term does not include the whole body.
- 1.20 "Person" means an individual, corporation, business trust, estate, trust, partnership, limited liability company, association, joint venture, public corporation, government or governmental subdivision, agency, or instrumentality, or any other legal or commercial entity.
- 1.21 "Physician" means an individual authorized to practice medicine or osteopathy under the law of any state.
- 1.22 "Physician Assistant" means a person who is qualified by academic and practical training to provide those certain patient services under the supervision, control, responsibility and direction of a licensed physician.
- 1.23 "Procurement Organization" means an eye bank, organ procurement organization, or tissue bank.
- 1.24 "Prospective Donor" means an individual who is dead or near death and has been determined by a procurement organization to have a part that could be medically suitable for transplantation, therapy, research, or education. The term does not include an individual who has made a refusal that is known by the procurement organization.
- 1.25 "Reasonably Available" means able to be contacted by a procurement organization without undue effort and willing and able to act in a timely manner consistent with existing medical criteria necessary for the making of an anatomical gift.
- 1.26 "Recipient" means an individual into whose body a decedent's part has been or is intended to be transplanted.
- 1.27 "Record" means information that is inscribed on a tangible medium or that is stored in an electronic or other medium and is retrievable in perceivable form.
- 1.28 "Refusal" means a record created under Section 2.3 of these Regulations that expressly states an intent to bar other persons from making an anatomical gift of an individual's body or part.
- 1.29 "Regulations" ["these Regulations"] means all sections of the Rules and Regulations Pertaining to Procurement Of Anatomical Gifts [R23-18.6.1-ANAT]. Unless specifically eited otherwise, all references contained herein shall be interpreted as pertaining to these Regulations.

- 1.30 "RIGL" means The Rhode Island General Laws, as amended.
- 1.31 "Sign" means, with the present intent to authenticate or adopt a record to:
 - (1) Execute or adopt a tangible symbol; or
 - (2) Attach to or logically associate with the record an electronic symbol, sound, or process.
- 1.32 "State" means a state of the United States, the District of Columbia, Puerto Rico, the United States Virgin Islands, or any territory or insular possession subject to the iurisdiction of the United States.
- 1.33 "Technician" means an individual determined to be qualified to remove or process parts by an appropriate organization that is licensed, accredited, or regulated under federal or state law. The term includes an enucleator.
- 1.34 "Tissue" means a portion of the human body other than an organ or an eye. The term does not include blood unless the blood is donated for the purpose of research or education.
- 1.35 "Tissue Bank" means a person that is licensed, accredited, or regulated under federal or state law to engage in the recovery, screening, testing, processing, storage, or distribution of tissue.
- 1.36 "Transplant Hospital" means a hospital that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients.

Section 2.0 SCOPE AND APPLICABILITY

2.1 Applicability. The Act and these Regulations apply to an anatomical gift or amendment to, revocation of, or refusal to make an anatomical gift, whenever made.

2.2 Persons Authorized to Receive an Anatomical Gift.

- (a) An anatomical gift may be made to the following persons named in the document of gift:
 - (1) A hospital; accredited medical school, dental school, college, or university; organ procurement organization; or other appropriate person, for research or education;
 - (2) Subject to Section 2.2(b) below, an individual designated by the person making the anatomical gift if the individual is the recipient of the part;
 - (3) An eye bank or tissue bank.
- (b) If an anatomical gift to an individual under Section 2.2(a)(2) cannot be transplanted into the individual, the part passes in accordance with Section 2.2(g) in the absence of a known, express, contrary indication by the person making the anatomical gift.
- (e) If an anatomical gift of one or more specific parts or of all parts is made in a document of gift that does not name a person described in Section 2.2(a) but identifies the purpose for which an anatomical gift may be used, the following rules apply:
 - (1) If the part is an eye and the gift is for the purpose of transplantation or therapy, the gift passes to the appropriate eye bank.
 - (2) If the part is tissue and the gift is for the purpose of transplantation or therapy, the gift passes to the appropriate tissue bank.
 - (3) If the part is an organ and the gift is for the purpose of transplantation or therapy, the gift passes to the appropriate organ procurement organization as custodian of the organ.
 - (4) If the part is an organ, an eye, or tissue and the gift is for the purpose of research or education, the gift passes to the appropriate procurement organization.
- (d) For the purpose of Section 2.2(e), if there is more than one purpose of an anatomical gift set forth in the document of gift but the purposes are not set forth in any priority, the gift shall be used for transplantation or therapy, if suitable. If the gift cannot be used for transplantation or therapy, the gift may be used for research or education.
- (e) If an anatomical gift of one or more specific parts is made in a document of gift that does not name a person described in Section 2.2(a) and does not identify the purpose of the gift, the gift passes in accordance with Section 2.2(g) and shall be used for transplantation or therapy, if suitable. If the gift cannot be used for transplantation or therapy, the gift may be used for research or education.
- (f) If a document of gift specifies only a general intent to make an anatomical gift by words such as "donor", "organ donor", or "body donor", or by a symbol or statement of similar import, the gift passes in accordance with Section 2.2(g) and shall be used for transplantation or therapy, if suitable. If the gift cannot be used for transplantation or therapy, the gift may be used for research or education.

- (g) For purposes of Section 2.2(b), (e), and (f) the following rules apply:
 - (1) If the part is an eye, the gift passes to the appropriate eye bank.
 - (2) If the part is tissue, the gift passes to the appropriate tissue bank.
 - (3) If the part is an organ, the gift passes to the appropriate organ procurement organization as custodian of the organ.
- (h) An anatomical gift of an organ for transplantation or therapy, other than an anatomical gift under Section 2.2(a)(2), passes to the organ procurement organization as custodian of the organ.
- (i) If an anatomical gift does not pass pursuant to Sections 2.2(a) through (h) or the decedent's body or part is not used for transplantation, therapy, research, or education, custody of the body or part passes to the person under obligation to dispose of the body or part.
- (j) A person shall not accept an anatomical gift if the person knows that the gift was not effectively made in accordance with these Regulations or if the person knows that the decedent made a refusal in accordance with the Act or these Regulations that was not revoked. For purposes of these Regulations, if a person knows that an anatomical gift was made on a document of gift, the person is deemed to know of any amendment or revocation of the gift or any refusal to make an anatomical gift on the same document of gift.
- (k) Except as otherwise provided in Section 2.2(a)(2), nothing in these Regulations affects the allocation of organs for transplantation or therapy.

2.3 Refusal to Make Anatomical Gift.

- (a) An individual may refuse to make an anatomical gift of the individual's body or part by:
 - (1) A record signed by:
 - (i) The individual; or
 - (ii) Subject to Section 2.3(b), another individual acting at the direction of the individual if the individual is physically unable to sign;
 - (2) The individual's will, whether or not the will is admitted to probate or invalidated after the individual's death: or
 - (3) Any form of communication made by the individual during the individual's terminal illness or injury addressed to at least two (2) adults, at least one of whom is a disinterested witness.
- (b) A record signed pursuant to Section 2.3(a)(1)(ii) shall:
 - (1) Be witnessed by at least two (2) adults, at least one of whom is a disinterested witness, who have signed at the request of the individual; and
 - (2) State that it has been signed and witnessed as provided in Section 2.3(b)(1).
- (c) An individual who has made a refusal may amend or revoke the refusal:
 - (1) In the manner provided in Section 2.3(a) for making a refusal;

- (2) By subsequently making an anatomical gift pursuant to the provisions of the Act that is inconsistent with the refusal; or
- (3) By destroying or canceling the record evidencing the refusal, or the portion of the record used to make the refusal, with the intent to revoke the refusal.
- (d) Except as otherwise provided in the Act or these Regulations, in the absence of an express, contrary indication by the individual set forth in the refusal, an individual's unrevoked refusal to make an anatomical gift of the individual's body or part bars all other persons from making an anatomical gift of the individual's body or part.

2.4 Preclusive Effect of Anatomical Gift, Amendment or Revocation.

- (a) Except as otherwise provided in this section, in the absence of an express, contrary indication by the donor, a person other than the donor is barred from making, amending, or revoking an anatomical gift of a donor's body or part if the donor made an anatomical gift of the donor's body or part in accordance with the provisions of the Act and these regulations.
- (b) A donor's revocation of an anatomical gift of the donor's body or part shall not be a refusal and does not bar another authorized person specified in these Regulations from making an anatomical gift of the donor's body or part.
- (e) If a person other than the donor makes an unrevoked anatomical gift of the donor's body or part, or an amendment to an anatomical gift of the donor's body or part, another person may not make, amend, or revoke the gift of the donor's body or part under the provisions of the Act or these Regulations.
- (d) A revocation of an anatomical gift of a donor's body or part by a person other than the donor does not bar another person from making an anatomical gift of the body or part under the provisions of the Act or these Regulations.
- (e) In the absence of an express, contrary indication by the donor or other person authorized to make an anatomical gift in accordance with the Act or these Regulations, an anatomical gift of a part is neither a refusal to give another part nor a limitation on the making of an anatomical gift of another part at a later time by the donor or another person.
- (f) In the absence of an express, contrary indication by the donor or other person authorized to make an anatomical gift in accordance with the Act or these Regulations, an anatomical gift of a part for one or more of the purposes set forth in Section 4.1 is not a limitation on the making of an anatomical gift of the part for any of the other purposes by the donor or any other person under the provisions of the Act or these Regulations.
- (g) If a donor who is an unemancipated minor dies, a parent of the donor who is reasonably available may revoke or amend an anatomical gift of the donor's body or part.
- (h) If an unemancipated minor who signed a refusal dies, a parent of the minor who is reasonably available may revoke the minor's refusal.

Section 3.0 GENERAL REQUIREMENTS

3.1 Search and Notification.

- (a) The following persons shall make a reasonable search of an individual who the person reasonably believes is dead or near death for a document of gift or other information identifying the individual as a donor or as an individual who made a refusal:
 - (4) A law enforcement officer, firefighter, paramedic, or other emergency rescuer finding the individual; and
 - (5) If no other source of the information is immediately available, a hospital, as soon as practical after the individual's arrival at the hospital.
- (b) If a document of gift or a refusal to make an anatomical gift is located by the search required by Section 3.1(a)(1) and the individual or deceased individual to whom it relates is taken to a hospital, the person responsible for conducting the search shall send the document of gift or refusal to the hospital.
- (e) A person is not subject to criminal or civil liability for failing to discharge the duties imposed by this section but may be subject to administrative sanctions.

3.2 Document of Gift - Delivery and Right to Examine.

- (a) A document of gift need not be delivered during the donor's lifetime to be effective.
- (b) Upon or after an individual's death, a person in possession of a document of gift or a refusal to make an anatomical gift with respect to the individual shall allow examination and copying of the document of gift or refusal by a person authorized to make or object to the making of an anatomical gift with respect to the individual or by a person to which the gift could pass pursuant to the provisions of the Act or these Regulations.

3.3 Presumption of Validity.

- (a) A document of gift is valid if executed in accordance with:
 - (1) The Act and these Regulations;
 - (2) The laws of the state where it was executed; or
 - (3) The laws of the state where the person making the anatomical gift was domiciled, has a place of residence, or was a national at the time the document of gift was executed.
- (b) If a document of gift is valid under this section, the laws of Rhode Island govern the interpretation of the document of gift.
- (c) A person may presume that a document of gift or amendment of an anatomical gift is valid unless that person knows that it was not validly executed or was revoked.

3.4 Immunity.

(a) A person that acts in accordance with these Regulation or with the applicable anatomical gift law of another state, or attempts in good faith to do so, is not liable for the act in a civil action, criminal prosecution, or administrative proceeding.

- (b) Neither the person making an anatomical gift nor the donor's estate is liable for any injury or damage that results from the making or use of the gift.
- (c) In determining whether an anatomical gift has been made, amended, or revoked pursuant to the Act, a person may rely upon representations of an individual listed in Section 5.1 relating to the individual's relationship to the donor or prospective donor unless the person knows that the representation is untrue.
- 3.5 *Organ Procurement*. All human organs for transplantation shall be obtained or procured in accordance with requirements specified in the *Minimum Procurement Standards For An Organ Procurement Organization*.¹

Section 4.0 ANATOMICAL GIFTS PRIOR TO DONOR'S DEATH

- 4.1 *Persons Authorized to Make Anatomical Gift.* Subject to the provisions of the Act and these Regulations, an anatomical gift of a donor's body or part may be made during the life of the donor for the purpose of transplantation, therapy, research, or education by:
 - (a) The donor, if the donor is an adult or if the donor is a minor and is:
 - (1) Emancipated; or
 - (2) Authorized under state law to apply for a driver's license because the donor is at least sixteen (16) years of age;
 - (b) An agent of the donor, unless the power of attorney for health care or other record prohibits the agent from making an anatomical gift;
 - (e) A parent of the donor, if the donor is an unemancipated minor; or
 - (d) The donor's guardian.

4.2 Manner of Making Anatomical Gift.

- (a) A donor may make an anatomical gift:
 - (1) By authorizing a statement or symbol indicating that the donor has made an anatomical gift to be imprinted on the donor's driver's license or identification card;
 - (2) In a will;
 - (3) During a terminal illness or injury of the donor, by any form of communication addressed to at least two (2) adults, at least one of whom is a disinterested witness; or
 - (4) As provided in Section 4.2(b).
- (b) A donor or other person authorized to make an anatomical gift under the Act or these Regulations may make a gift by authorizing inclusion of the donor on a donor registry, a donor card or other record signed by the donor or other person making the gift. If the donor or other person is physically unable to sign a record, the record may be signed by another individual at the direction of the donor or other person and shall:

⁴ Available from: The Organ Procurement and Transplantation Network, Post Office Box 2484, Richmond, VA 23218 [www.optn.org].

- (1) Be witnessed by at least two (2) adults, at least one of whom is a disinterested witness, who have signed at the request of the donor or the other person; and
- (2) State that it has been signed and witnessed as provided in Section 4.2(b)(1).
- (e) Revocation, suspension, expiration, or cancellation of a driver's license or identification card upon which an anatomical gift is indicated does not invalidate the gift.
- (d) An anatomical gift made by will takes effect upon the donor's death whether or not the will is probated. Invalidation of the will after the donor's death does not invalidate the gift.

4.3 Amending or Revoking Anatomical Gift.

- (a) Subject to the provisions of the Act and these Regulations, a donor or other person authorized to make an anatomical gift may amend or revoke an anatomical gift by:
 - (1) A record signed by:
 - (i) The donor;
 - (ii) The other person so authorized; or
 - (iii) Subject to Section 4.3(b), another individual acting at the direction of the donor or the other person so authorized if the donor or other person is physically unable to sign; or
 - (2) A later-executed document of gift that amends or revokes a previous anatomical gift or portion of an anatomical gift, either expressly or by inconsistency.
- (b) A record signed pursuant to Section 4.3(a)(1)(iii) shall:
 - (1) Be witnessed by at least two (2) adults, at least one of whom is a disinterested witness, who have signed at the request of the donor or the other person; and
 - (2) State that it has been signed and witnessed as provided in Section 4.3(b)(1).
- (e) Subject to the provisions of the and these regulations, a donor or other person authorized to make an anatomical gift may revoke an anatomical gift by the destruction or cancellation of the document of gift, or the portion of the document of gift used to make the gift, with the intent to revoke the gift.
- (d) A donor may amend or revoke an anatomical gift that was not made in a will by any form of communication during a terminal illness or injury addressed to at least two (2) adults, at least one of whom is a disinterested witness.
- (e) A donor who makes an anatomical gift in a will may amend or revoke the gift in the manner provided for amendment or revocation of wills or as provided in the Act and these Regulations.

Section 5.0 ANATOMICAL GIFTS OF DECEDENT'S BODY OR PART

5.1 Persons Authorized to Make Anatomical Gift.

- (a) Subject to Sections 5.1(b) and (e) and unless barred by the Act or these Regulations, an anatomical gift of a decedent's body or part for purpose of transplantation, therapy, research, or education may be made by any member of the following classes of persons who is reasonably available, in the order of priority listed:
 - (1) An agent of the decedent at the time of death who could have made an anatomical gift pursuant to the Act or these Regulations immediately before the decedent's death:
 - (2) The spouse of the decedent or the certified domestic partner of the decedent as defined in RIGL 36-12-1(3) and 45-19-4.3(b) or any other provision of state law;
 - (3) Adult children of the decedent:
 - (4) Parents of the decedent;
 - (5) Adult siblings of the decedent;
 - (6) Adult grandchildren of the decedent;
 - (7) Grandparents of the decedent;
 - (8) An adult who exhibited special care and concern for the decedent, who is familiar with the decedent's personal values, and who had maintained regular contact with the decedent prior to his or her death; provided, however, it shall not include any medical personnel earing for the decedent at the time of or immediately leading up to the decedent's death; and
 - (9) The persons who were acting as the guardians of the person of the decedent at the time of death.
- (b) If there is more than one member of a class listed in Section 5.1(a) which is entitled to make an anatomical gift, an anatomical gift may be made by a member of the class unless that member or a person to which the gift may pass under the provisions of the Act or these Regulations knows of an objection by another member of the class. If an objection is known, the gift may be made only by a majority of the members of the class who are reasonably available.
- (c) A person may not make an anatomical gift if, at the time of the decedent's death, a person in a prior class under Section 5.1(a) is reasonably available to make or to object to the making of an anatomical gift.

5.2 Manner of Making, Amending or Revoking Anatomical Gift.

- (a) A person authorized to make an anatomical gift under Section 5.1 may make an anatomical gift by a document of gift signed by the person making the gift or by that person's oral communication that is electronically recorded or is contemporaneously reduced to a record and signed by the individual receiving the oral communication.
- (b) Subject to Section 5.2(c), an anatomical gift by a person authorized under Section 5.1 may be amended or revoked orally or in a record by any member of a prior class who is

reasonably available. If more than one member of the prior class is reasonably available, the gift made by a person authorized under Section 5.1 may be:

- (1) Amended only if a majority of the reasonably available members agree to the amending of the gift; or
- (2) revoked only if a majority of the reasonably available members agree to the revoking of the gift or if they are equally divided as to whether to revoke the gift.
- (c) A revocation under Section 5.2(b) is effective only if, before an incision has been made to remove a part from the donor's body or before invasive procedures have begun to prepare the recipient, the procurement organization, transplant hospital, physician, physician assistant or technician knows of the revocation.

Section 6.0 HOSPITAL, ORGAN PROCUREMENT ORGANIZATION, MEDICAL EXAMINER AND DONOR REGISTRY

6.1 Coordination of Procurement and Use. Each hospital in Rhode Island shall enter into agreements or affiliations with procurement organizations for coordination of procurement and use of anatomical gifts.

6.2 Rights and Duties of Procurement Organization and Others.

- (a) When a hospital refers an individual at or near death to a procurement organization, the organization shall make a reasonable search of the records of the Department of Motor Vehicles and any donor registry that it knows exists for the geographical area in which the individual resides to ascertain whether the individual has made an anatomical gift.
- (b) A procurement organization shall be allowed reasonable access to information in the records of the Rhode Island Donor Registry to ascertain whether an individual at or near death is a donor.
- (e) When a hospital refers an individual at or near death to a procurement organization, the organization may conduct any reasonable examination necessary to assess the medical suitability of a part that is or could be the subject of an anatomical gift for transplantation, therapy, research, or education from a donor or a prospective donor. During the examination period, measures necessary to maintain the potential medical suitability of the part may not be withdrawn unless the hospital or procurement organization knows that the individual expressed a contrary intent.
- (d) Unless otherwise prohibited, at any time after a donor's death, the person to which a part passes under the Act or these Regulations may conduct any reasonable examination necessary to assess the medical suitability of the body or part for its intended purpose.
- (e) Unless otherwise prohibited, an examination under Sections 6.2(e) or (d) may include an examination of all medical and dental records of the donor or prospective donor.
- (f) Upon the death of a minor who was a donor or had signed a refusal, unless a procurement organization knows the minor is emancipated, the procurement organization shall conduct a reasonable search for the parents of the minor and provide the parents with an opportunity to revoke or amend the anatomical gift or revoke the refusal.

- (g) Upon referral by a hospital under Section 6.2(a), a procurement organization shall make a reasonable search for any person listed in Section 5.1 having priority to make an anatomical gift on behalf of a prospective donor. If a procurement organization receives information that an anatomical gift to any other person was made, amended, or revoked, it shall promptly advise the other person of all relevant information.
- (h) Subject to the provisions of the Act and these Regulations, the rights of the person to which a part passes under Section 2.2 are superior to the rights of all others with respect to the part. The person may accept or reject an anatomical gift in whole or in part. Subject to the terms of the document of gift as specified in the Act and these Regulations, a person that accepts an anatomical gift of an entire body may allow embalming, burial or cremation, and use of remains in a funeral service. If the gift is of a part, the person to which the part passes under Section 2.2, upon the death of the donor and before embalming, burial, or cremation, shall cause the part to be removed without unnecessary mutilation.
- (i) Neither the physician who attends the decedent at death nor the physician who determines the time of the decedent's death may participate in the procedures for removing or transplanting a part from the decedent.
- (j) A physician, physician assistant or technician may remove a donated part from the body of a donor that the physician, physician assistant or technician is qualified to remove.
- 6.3 Cooperation Between Medical Examiner and Procurement Organization. A medical examiner shall cooperate with procurement organizations to maximize the opportunity to recover anatomical gifts for the purpose of transplantation, therapy, research, or education.

6.4 Facilitation of Anatomical Gift From Decedent.

- (a) The medical examiner or his or her designee shall provide the federally designated organ procurement organization and other nonprofit federally registered eye and tissue banks, in a timely manner, all information necessary to facilitate organ and tissue donation including, but not limited to, names and available contact information of individuals whose deaths have been reported to the medical examiner's office and jurisdiction accepted.
- (b) The medical examiner may release and permit the removal of a part from a body within that official's custody, for transplantation or therapy, if:
 - (1) The official has received a request for the part from a hospital, physician, surgeon, or procurement organization;
 - (2) A donation has been authorized in accordance with Section 4.2 or Section 5.1;
 - (3) The official does not know of a refusal or contrary indication by the decedent or objection by a person having authority to act as listed in Section 5.1;
 - (4) The removal will be by a physician, surgeon, physician assistant or technician; but in the case of eyes, by one of them or by an enucleator;
 - (5) The removal will not interfere with any autopsy, investigation, procedure, or other additional activity as deemed necessary by the medical examiner required to arrive at

a reasonable cause and manner of death;

- (6) The removal will be in accordance with accepted medical standards; and
- (7) Cosmetic restoration will be done, if appropriate.
- (e) The medical examiner, or his or her designee, may permit the removal of the anatomical gift to occur at the medical examiner's office.
- (d) A permanent record of the names of the decedent, the person making the request, the date and purpose of the request, the part requested, and the person to whom it was released shall be made by the hospital/physician/physician assistant/technician (enucleator) and forwarded to the medical examiner for his or her records.
- (e) The medical examiner, or his or her designee, shall be present during the removal of the anatomical gift if in his or her judgment such attendance would, in the opinion of the medical examiner or his or her designee, facilitate a donation that would otherwise be denied.
- (f) The medical examiner, or his or her designee, shall only deny removal of the anatomical gift after explaining in writing or verbally with subsequent written documentation to the federally designated organ procurement organization and other nonprofit federally registered eye and tissue banks, reasons for determining that those tissues or organs may be involved in the cause of death.

6.5 Donor Registry.

- (a) A donor registry shall:
 - (1) Allow a donor or other person authorized pursuant to the Act or these Regulations to include an individual on the donor registry who has made an anatomical gift;
 - (2) Be accessible to a procurement organization to allow it to obtain relevant information on the donor registry to determine, at or near death of the donor or a prospective donor, whether the donor or prospective donor has made an anatomical gift; and
 - (3) Be accessible for purposes of Sections 6.5(a)(1) and (2) seven days a week on a twenty-four (24) hour basis.
- (b) Personally identifiable information on a donor registry about a donor or prospective donor shall not be used or disclosed without the express consent of the donor, prospective donor, or person that made the anatomical gift for any purpose other than to determine, at or near death of the donor or prospective donor, whether the donor or prospective donor has made an anatomical gift.

Section 7.0 **PROHIBITIONS AND PENALTIES**

7.1 Sale or Purchase of Parts Prohibited.

- (a) Except as otherwise provided in Section 7.1(b), a person that for valuable consideration, knowingly purchases or sells a part for transplantation or therapy if removal of a part from an individual is intended to occur after the individual's death commits a felony and upon conviction is subject to a fine not exceeding fifty thousand dollars (\$50,000) or imprisonment not exceeding five (five) years, or both.
- (b) A person may charge a reasonable amount for the removal, processing, preservation, quality control, storage, transportation, implantation, or disposal of a part.
- 7.2 Other Prohibited Acts. A person that, in order to obtain a financial gain, intentionally falsifies, forges, conceals, defaces, or obliterates a document of gift, an amendment or revocation of a document of gift, or a refusal commits a felony and upon conviction is subject to a fine not exceeding fifty thousand dollars (\$50,000) or imprisonment not exceeding five (5) years, or both.

Section 8.0 SEVERABILITY

- 8.1 If any section, subsection, sentence, clause, phrase or portion of the Act or these Regulations is for any reason held invalid or unconstitutional by any court of competent jurisdiction, that portion shall be deemed a separate, distinct and independent provision and this holding shall not affect the validity of the remaining portions of the Act or these Regulations.
- 8.2 Nothing contained in the Act or these Regulations shall be construed to affect any other provisions of Title 23 of the Rhode Island General Laws, as amended.

OrganDonorRegulations_FilingVersion_29Nov2007.doc