

REGULATIONS IMPLEMENTING THE VIRGINIA ORGAN AND TISSUE  
DONOR REGISTRY

CHAPTER 475.

REGULATIONS IMPLEMENTING THE VIRGINIA ORGAN  
AND TISSUE DONOR REGISTRY

Article 1.

Definitions and General Information.

12 VAC 5-475-10. Definitions.

The following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

“Agent” means an adult appointed by the declarant under an advance directive, executed or made in accordance with the provisions of § [54.1-2983](#), to make health care decisions for him, including decisions relating to visitation, provided the advance directive makes express provisions for visitation and subject to physician orders and policies of the institution to which the declarant is admitted. The declarant may also appoint an adult to make, after the declarant's death, an anatomical gift of all or any part of his body pursuant to Article 2 (§ [32.1-289](#) et seq.) of Chapter 8 of Title 32.1.

“Anatomical gift” or “organ donation” means a donation of organs, tissues, or eyes or all or any part of a human body to take effect upon or after death.

“Board” means the State Board of Health.

“Commissioner” means the State Health Commissioner, his duly designated officer or agent.

REGULATIONS IMPLEMENTING THE VIRGINIA ORGAN AND TISSUE  
DONOR REGISTRY

“Decedent” means a deceased individual and includes a stillborn infant or fetus.

“Department” means the State Department of Health.

“Document of gift” means a card, a statement attached to or imprinted on a motor vehicle driver’s or chauffeur’s license, or the record of the individual’s motor vehicle driver’s or chauffeur’s license, a will, an advance directive, or other writing used to make an organ donation or an anatomical gift. “Document of gift” also includes a record of the donor’s gift stored in a registry.

“Donor” means an individual who makes a donation of organs, tissues, or eyes or an anatomical gift of all of his body.

“Disseminate” means to release, transfer, or otherwise communicate information orally, in writing, or by electronic means.

“Eye bank” means an agency accredited by the Eye Bank Association of America operating in this Commonwealth.

“Guardian” means a person appointed by the court who is responsible for the personal affairs of an incapacitated person, including responsibility for making decisions regarding the person's support, care, health, safety, habilitation, education, and therapeutic treatment, and, if not inconsistent with an order of commitment, residence. Where the context plainly indicates, the term includes a "limited guardian" or a "temporary guardian." The term includes a local or regional program designated by the Department for the Aging as a public

REGULATIONS IMPLEMENTING THE VIRGINIA ORGAN AND TISSUE  
DONOR REGISTRY

guardian pursuant to Article 2 (§ 2.1-373.10 et seq.) of Chapter 24 of Title 2.1 of the Code of Virginia.

“Informed consent” means the knowing and voluntary agreement, obtained without undue influence or any use of force, fraud, deceit, duress, or other form of constraint or coercion, of a person who is capable of exercising free power of choice.

“Organ procurement organization” means an agency certified by the United States Health Care Financing Administration as an organ procurement organization.

“Part” means an organ, tissue, eye, bone, artery, blood, fluid or other portion of a human body.

“Personal information” means all information that describes, locates or indexes anything about an individual, as defined in §2.1-379 of the Code of Virginia.

“Procurement” means the recovery of any donated part by a physician licensed, accredited, or approved under the laws of any state.

“Registry” means the Organ and Tissue Donor Registry for the Commonwealth, which shall be administered by the Department of Health in accordance with §32.1-292.2 of the Code of Virginia. The registry shall maintain and update, as needed, the pertinent information on all Virginians who have indicated a willingness to donate.

REGULATIONS IMPLEMENTING THE VIRGINIA ORGAN AND TISSUE  
DONOR REGISTRY

“Tissue bank” means an agency accredited by the American Association of Tissue Banks operating in this Commonwealth.

“UNOS” means the United Network for Organ Sharing.

“VTC” means the Virginia Transplant Council, a program within the Virginia Department of Health, which exists to promote and coordinate educational and information activities as related to the organ, tissue, and eye donation process and transplantation in the Commonwealth of Virginia.

12 VAC 5-475-20. Authority.

Article 2, Chapter 8 of Title 32.1 of the Code of Virginia establishes the creation of an organ and tissue donor registry. Specifically, §32.1-292.2 directs the Board of Health, in consultation with the Virginia Transplant Council (VTC), to promulgate regulations necessary to administer the registry, including maintaining, and updating as needed, the pertinent information on all Virginians who have indicated a willingness to donate organs, tissues, or eyes or all or any part of the human body in accordance with §32.1-290. Acts 2000, cc. 481 and 490, cl. 2 provide “that the Board of Health shall promulgate regulations to implement the provisions of this act within 280 days of enactment.” Section 32.1-12 of the Code of Virginia empowers the Board to adopt such regulations as are necessary to carry out provisions of laws of the Commonwealth administered by the Commissioner of the Department of Health.

REGULATIONS IMPLEMENTING THE VIRGINIA ORGAN AND TISSUE  
DONOR REGISTRY12 VAC 5-475-30. Purpose.

These regulations are designed to accomplish the tasks listed in §32.1-292.2 (C.) (1) and (2) of the Code of Virginia by establishing procedures for the administration of the registry.

12 VAC 5-475-40. Administration.

- A. The Board has the responsibility for promulgating regulations, in consultation with the VTC, pertaining to the administration of the organ and tissue donor registry.
- B. The Commissioner is the executive officer for the State Board of Health with the authority of the Board when it is not in session, subject to the rules and regulations of and review by the Board.
- C. The VTC, as delegated by the Board pursuant to 32.1-292.2 (D) (2) of the Code of Virginia, is responsible to analyze registry data under research protocols directed toward determination and identification of means to promote and increase organ, eye, and tissue donation within the Commonwealth.
- D. Confidentiality – All persons responsible for the administration of the organ and tissue donor registry shall ensure that the registry and all information therein shall be confidential in accordance with §32.1-127.1:03 of the Code of Virginia and applicable federal law.

REGULATIONS IMPLEMENTING THE VIRGINIA ORGAN AND TISSUE  
DONOR REGISTRY

12 VAC 5-475-50. Access.

The registry and all information therein shall be accessible 24 hours a day and only to the Department and the specific designees of accredited organ procurement organizations, eye banks and tissue banks operating in or serving Virginia and which are members of the VTC, for the purpose of identifying a potential donor according to the provisions of §32.1-127.1, subsection F of §46.2-342, and §32.1-292.2.

The name of such designees shall be provided to the VTC. All other persons or entities shall be prohibited from having access to the registry. If at any time the designee is unable to carry out his responsibilities with respect to the registry, a replacement shall be selected and the VTC shall be notified of such replacement.

All accredited organ procurement organizations, eye banks, and tissue banks with authorized access to the registry shall be required to report annually to the VTC the following outcome data: (a) the number of times the registry is accessed; (b) the number of times access to the registry results in an unsuccessful search (i.e., the individual is not a member of the registry); (c) the number of times an organ, tissue or eye procurement proceeds solely from accessing the registry; (d) the number of times the next of kin's consent is obtained in addition to a successful search of the registry; (e) the number of times donation of organs, tissue, or eyes occurred as a result of alternative donation designation documentation; and (f) the number of times the next of kin's

REGULATIONS IMPLEMENTING THE VIRGINIA ORGAN AND TISSUE  
DONOR REGISTRY

consent is obtained without accessing the registry. Such reports shall be made on a form to be provided by the VTC (VTC-2).

Article 2.Registry Information12 VAC 5-475-60. Registry Membership.

Those persons 18 years and older who have indicated a willingness to donate in accordance with §32.1-290 and have completed the required registration form (VTC-1) shall be recorded in the registry. Persons under the age of 18 may enter the registry upon completion of the registration form and only with the written consent of his parent or legal guardian. No person may enter another person in the registry.

Those persons who have indicated a willingness to donate on their driver's license or personal identification card as authorized by the Department of Motor Vehicles will be automatically entered into the registry. Through inter-agency agreement, the Department of Motor Vehicles will assist the department by electronically providing this information to the registry on a daily basis. The VTC shall contact any such self-identified persons by United States mail regarding notification of membership to the registry and request the completion of the registration form (VTC-1).

12 VAC 5-475-70. Data to be Recorded.

The following information shall be recorded in the registry: the donor's full name, address (include county or independent city of residence with zip code),

REGULATIONS IMPLEMENTING THE VIRGINIA ORGAN AND TISSUE  
DONOR REGISTRY

telephone number, date of birth, age, sex, race, driver's license number, or unique identification number. If the donor is under the age of 18, the name, telephone number, address, and unique identification number of the donor's parent or legal guardian shall be recorded.

Information shall be recorded by completing the Virginia Organ and Tissue Donor Registry Registration Form (VTC-1).

12 VAC 5-475-80. Removal from the Registry.

A person who has joined the registry may have his name removed by filing an appropriate form (VTC-0) with the VTC or in accordance with subsections E and F of §32.1-290 or subsection G of §46.2-342.

The name of a person entered in the registry who has died shall be removed from the registry within 90 days of notification of death by the Virginia Office of Vital Records and Health Statistics.

Article 3.Use and Dissemination of Registry Information.12 VAC 5-475-90. Use.

The designees of accredited organ procurement organizations, eye banks and tissue banks with authorized access to the registry shall have an organizational and/or individual pass code assigned by the VTC to gain entry to the registry via the VTC website.

Once entry to the registry has been established, the designees shall enter the full name of the decedent, the decedent's date of birth, the decedent's drivers



REGULATIONS IMPLEMENTING THE VIRGINIA ORGAN AND TISSUE  
DONOR REGISTRY

license number, the decedent's unique identification number, or any combination thereof, to verify whether the decedent made a donor designation in the registry.

Once the decedent's donor designation has been verified, the designees shall include the intent to donate as part of the donor record maintained by the accredited organ procurement organization, eye bank and tissue bank.

If the decedent is not in the registry, the designees shall exit the registry. Designees shall not perform a search of the registry on any other person other than the decedent.

12 VAC 5-475-100. Dissemination.

The accredited organ procurement organizations, eye banks and tissue banks with authorized access to the registry may disclose the decedent's documented donation designation to the decedent's next of kin, the nearest available relative, a member of the decedent's household, an individual with an affinity relationship, and the primary treating physician, in order to demonstrate the decedent's wish to donate in accordance with §32.1-290, §46.2-342, §54.2-2984, and §54.1-2986 of the Code of Virginia.

The VTC may disclose to the DMV the donor designation on those persons who are recorded in the registry in order that the driver's record accurately reflect those persons' wishes to donate pursuant to subsection E and F of §46.2-342 of the Code of Virginia.