

ORGAN, TISSUE, AND EYE DONATION PROCESS

- 1. REASON FOR ISSUE.** This Veterans Health Administration (VHA) Handbook describes the procedures for processing referrals to local procurement organizations, which encompass solid organ, tissue, and eye donation.
- 2. SUMMARY OF CHANGES.** This is a new Handbook defining the parameters of Organ, Tissue, and Eye Donation within VHA.
- 3. RELATED ISSUES.** VHA Directive 1100 (to be published).
- 4. RESPONSIBLE OFFICE.** The Office of Patient Care Services, Chief Consultant, Medical-Surgical Services (111) is responsible for the contents of this VHA Handbook. Questions may be referred to the Department of Veterans Affairs (VA) National Transplant Program at (202) 461-7130.
- 5. RECISSIONS.** VHA Directive 2000-003, dated February 17, 2000, is rescinded.
- 6. RECERTIFICATION.** This VHA Handbook is scheduled for recertification on or before the last working day of April 2014.

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ORGAN, TISSUE, AND EYE DONATION PROCESS

1. PURPOSE

This Veterans Health Administration (VHA) Handbook defines procedures for Department of Veterans Affairs (VA) medical centers to enter into Agreements with local Procurement Organizations (encompasses solid organ, tissue bank, and eye bank) for donation and establishes standard language for use in entering into Agreements.

2. BACKGROUND

a. The Omnibus Budget Reconciliation Act (OBRA) of 1986 amended the Social Security Act to include several provisions relating to organ transplantation. Section 1138(a)(1), of the Social Security Act (Title 42 United States Code (U.S.C.) 1320b-8) requires medical centers to establish written protocols for the identification and referral of potential donors to a certified procurement organization.

b. The Centers for Medicare and Medicaid Services (CMS) has implemented additional regulation(s) for facilities wishing to maintain participation in the Medicare program. VA is not required to comply with these regulations; however, to enhance and maintain VA's transplant programs, VHA voluntarily complies with the CMS regulation(s) to the extent possible under the law.

c. The revised regulation (42 CFR 482.45) states that the medical centers must have and implement written protocols that:

(1) Incorporate an agreement with a procurement organization, and contact the procurement organization and/or a designated third-party, in a timely manner about individual deaths or who are near death (imminent death).

(2) Include cooperation with at least one tissue bank and one eye bank that is:

(a) Registered with the FDA; and

(b) Not subject to any regulatory action to cease, suspend, or otherwise limit operations.

(3) Ensure that the medical center works with the procurement organization to inform families of patients about the patient's decision to donate or, as applicable under state law, the family's option to donate or decline donation of organs, tissues, and/or eyes.

(4) Designate the individual who will approach the family who must be either a procurement organization representative or trained designated requestor.

(5) Encourage discretion and sensitivity when dealing with families and potential donors.

(6) Ensure that the medical center staff works cooperatively with the procurement organizations in educating staff on donation issues, reviewing death records, and maintaining potential donors while necessary testing and placement take place.

d. CMS regulation requires the release of patient information to procurement organizations. While VHA had authority under the Privacy Act, 5 U.S.C. 552a, and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule to allow for the disclosure of health information to procurement organizations for suitability for donation, there were limitations posed by other Federal statutes. Congress has amended 38 U.S.C. 5701(k)(1)(A) and 38 U.S.C. 7332(b)(2)(E), to allow disclosure of all pertinent health care information to determine suitability for donation.

e. VA medical centers must be in compliance with Joint Commission Standard TS.01.01.01, TS.02.01.01, Standard RI.01.05.01, and Standard PI.02.01.01, which includes implementation of policies and procedures, developed with the medical staff's participation, for the procuring and donating of organs and other tissues.

3. DEFINITIONS

a. **Agreement.** An Agreement is defined as a document that a VA facility develops in collaboration with a procurement organization (see par. 9). This agreement must detail the responsibilities and obligations of the parties with regard to identifying potential donors and facilitating the donation process.

b. **Death.** Death, or deceased, can be established by either neurological criteria (brain death) or cardiopulmonary criteria (cardiac death). Brain death is defined as the irreversible cessation or loss of all function of the brain, including the brainstem. Cardiac death is defined as the irreversible cessation of circulatory and respiratory function. In both cases, "irreversible" means that function will not resume spontaneously and will not be restarted artificially. ***NOTE: The criteria applied by clinicians to determine death is established by state law.***

c. **VA Facility-Designated Requestor or Liaison.** VA's Facility-Designated Requestor or Liaison is an identified VHA facility-based staff member who assists the representative of the procurement organization. ***NOTE: If a facility identifies a "designated requestor," that individual must complete a course offered and approved by the procurement organization that provides training in the methodology for approaching potential donor families.***

d. **Donation after Cardiac Death (DCD) or Controlled DCD.** DCD is the voluntary decision of a patient or valid surrogate to donate the patient's organs following the death of the patient after voluntary removal of unwanted life-sustaining therapies. ***NOTE: "Uncontrolled" DCD pertains to organ donation under circumstances when patients unexpectedly suffer cardiac arrest from which they do not survive.***

e. **Near Death.** Near death refers to a situation when, in the clinical judgment of the patient's health care provider and based on defined clinical triggers, the patient's death is imminent.

f. **Procurement Organization.** Procurement organization refers to an Organ Procurement Organization (OPO), an eye bank, or a tissue bank.

(1) An OPO must meet the applicable requirements of the Public Health Service Act (42 U.S.C. 273(b)(1)), and be certified or recertified by the Department of Health and Human Services (HHS).

(2) Eye banks and tissue banks are regulated by HHS under section 361 of the Public Health Service Act (42 U.S.C. 264) and 21 CFR Part 1271.

g. **OPO Coordinator.** An OPO Coordinator is an OPO staff member who assists in the donor management, suitability determination and family services coordination. These individuals facilitate the donation consent process, coordinate the surgical procurement, assume immediate responsibility for the preservation and distribution of the organs to transplant centers according to guidelines established by United Network for Organ Sharing (UNOS).

h. **Potential Donor.** The potential donor is an individual who suffers from a condition with terminal prognosis; is at a point where death has occurred or is imminent; and, in the opinion of the attending physician, and in consultation with the procurement coordinator, meets the local donor criteria. A potential donor may also be an individual who has indicated a preference to donate. *NOTE: An individual who expresses a preference against donation or who has such a preference documented in the individual's health record, does not qualify as a potential donor.*

4. SCOPE

a. It is VHA's goal that all VA facilities enter into Agreements with their local procurement organizations to identify potential donors and notify family members of the patient's decision to donate or, as applicable under state law, the family's options to donate or to decline donation of organs, tissue, and/or eyes.

b. Further, specific procedures must be developed in order for donation and procurement to proceed in accordance with the highest medical and ethical standards.

5. RESPONSIBILITY OF FACILITY DIRECTOR

a. The facility Director is responsible for ensuring:

(1) The facility enters into an Agreement with the appropriate specific procurement organization(s) to address donation procedures. *NOTE: In some areas, the procurement organization determines the medical suitability for tissue and eye donations, in effect acting as the "gatekeeper" for the tissue and eye banks. If an OPO is performing this duty, it must be noted in the agreement with the facility.*

(2) The facility verifies, in January of each calendar year, with the Food and Drug Administration (FDA) that:

(a) An eye bank and tissue bank has complied with FDA registration requirement of 21 CFR Part 1271, and

(b) The registration status is active before permitting an eye bank or tissue bank to receive protected health information.

(3) All disclosures of protected health information to procurement organizations are tracked to meet the accounting of disclosure requirements as outlined in VHA Handbook 1605.1.

(4) The procurement organization is notified of all deaths, regardless of whether the facility has full ventilator capability, ventilator capability only for patients who are to be transferred to a larger facility, or no ventilator capability.

(5) The appropriate facility staff work with the OPO, eye bank, or tissue bank to determine “maintenance of the donor” parameters, relative costs, and agreed upon reimbursement arrangements. These issues are to be addressed in the agreement with the OPO (see par. 9).

(6) Educational materials regarding organ donation and donor registration are developed in collaboration with the local OPO. *NOTE: Education materials and indication of preferences for donation may be incorporated into the usual clerical functions at enrollment, inpatient admission or stay, or new patient orientation, or outpatient encounters.*

(7) A written procedure is in place for notifying the family of each potential donor of the patient’s decision to donate or, as applicable under state law, the family’s option to donate or decline to donate organs, tissue or eyes (see par. 10). *NOTE: The OPO or eye or tissue bank should collaborate with facility staff establishing this procedure.*

(8) A written protocol is in place that:

(a) Meets the intent of The Joint Commission Standard TS.01.01.01 and TS.02.01.01 to identify potential organ, tissue, and/or eye donors (see subpar. 11e); and

(b) Implements the policies and procedures set forth in this Handbook. For active duty patients in a VA facility, Department of Defense (DOD) Directive Number 6465.3, May 4, 2004—Organ and Tissue Donation, or subsequent guidance is provided by DOD. *NOTE: A copy of DOD Directive 6464.3, can be located at: <http://www.dtic.mil/whs/directives/corres/pdf/646503p.pdf>. DOD defines “next-of-kin” differently than VA defines “surrogate.”*

(9) A written policy on processing donation referrals is in place. This policy is to include guidelines for working with the procurement organizations to improve the donor pool and maintain potential donors (see par. 11).

(10) Procurement of organs, or eyes takes place only after the donor is declared deceased by an attending physician not affiliated with any of the organ procurement or transplant teams. *NOTE: The criteria applied by clinicians to determine death is established by state law.*

(a) In accordance with applicable state law, death may be declared on the basis of cardiopulmonary criteria (cardiac death) or neurologic criteria (brain death).

(b) Donation of organs, tissues, or eyes from cardiac death patients can be the result of the patient's and/or family's choice, but must not be the sole purpose of life support withdrawal. DCD should only take place to honor this choice. **NOTE:** *Discretion and sensitivity must be exercised along with respect for individual circumstances, views, and beliefs of patients and families of potential donors.*

(c) Medical Examiner cases do not preclude donation. A case must be referred to the Medical Examiner in the usual way and follow the same procedure in reporting these deaths to the procurement organization, as donation may be an option. The procurement organization contacts the Medical Examiner regarding the release of suitable organs, tissues or eyes for donation.

(11) An operating room with appropriate staff and equipment is provided for performing recovery of major vital organs, tissue, and eyes. For tissue and eye recovery, the morgue or bed side may be used in lieu of the operating room. Without facilities for organ, tissue, or eye recovery, the procurement organization, if possible, makes arrangements for transfer of the donor to an appropriate facility.

(12) The procedure for notifying family members is effected in collaboration with the procurement organization (see par. 10).

b. In any VA facility in which any type of solid organ transplant is performed, the facility Director is responsible for ensuring membership in the Organ Procurement and Transplantation Network (OPTN). In addition, organ-transplant-related data must be provided, as requested by the OPTN, the Scientific Registry, OPOs, and HHS.

6. RESPONSIBILITY OF THE FACILITY CHIEF OF STAFF AND NURSE EXECUTIVE

The facility Chief of Staff and the Nurse Executive are responsible for:

- a. Implementing, enforcing and monitoring the protocol.
- b. Identifying individual(s) to be responsible for notifying the procurement organization of a death or imminent death of a patient.
- c. Identifying hospital staff to be the VA liaison or trained designated requestors.
- d. Ensuring there is a trained liaison or trained requestor coverage for all shifts.
- e. Ensuring that facility staff is aware of the rights of the patient and patient's family to make, or decline to make, organ, tissue, and/or eye donations.

7. RESPONSIBILITY OF THE VA FACILITY-DESIGNATED REQUESTOR OR LIAISON

The VA Facility-Designated Requestor or Liaison is responsible for:

- a. Notifying the procurement organization, or third-party designated by the organ, tissue and/or eye bank of a patient's death or that a death is imminent. The liaison must make and document the call. **NOTE:** *A sample form is available at: <http://vaww.va.gov/organdonation>. This is an internal web site and is not available to the public.*
- b. Collaborating in the donation consent process with the procurement coordinator(s).
- c. Ensuring procurement coordinator(s) have the information required to make donor suitability determinations.
- d. Ensuring relevant electronic VA files are available for viewing by procurement coordinator(s).

8. RESPONSIBILITY OF THE FACILITY ATTENDING PHYSICIAN

The facility attending physician, or designee, is responsible for:

- a. Notifying the facility Director, the Chief of Staff, the Nurse Executive, and the Anesthesiologist that organ procurement is contemplated after death.
- b. Documenting any discussion regarding donation after cardiac death in the patient's electronic health record.

9. AGREEMENTS

Each facility must enter into an Agreement(s) with specific procurement organizations to address the following donation procedures. **NOTE:** *In some areas, the OPO determines the medical suitability for tissue and eye donations, in effect acting as the "gatekeeper" for the tissue and eye banks. If an OPO is performing this duty, it must be noted in the agreement with the VA facility.* The agreement must:

- a. Indicate that the procurement organization is insured for professional liability for services and activities performed under the agreement, and that the same or similar coverage exists for its directors, officers, employees, physicians, independent contractors, agents, and representatives performing services under the agreement. The nature and amount of such insurance must be stated in the agreement.
- b. State that the procurement organization will indemnify and hold VA harmless from any and all liability for loss, claims, damages, injury, or death, including all costs, expenses, and reasonable attorney fees, caused by or resulting from the acts or omissions of the procurement

organization, its directors, officers, employees, physicians, independent contractors, agents, or representatives for services and activities performed under the agreement.

c. Ensure that the procurement organization coordinators undergo the appropriate level of background screening required by VA Directive and Handbook 0710, VA Directive and Handbook 6500, the Personal Identify Verification (PIV) Program, Federal Information Processing Standard (FIPS) 201, and the Federal Information Security Management Act (FIMSA).

10. COMMUNICATING WITH FAMILY MEMBERS OF POTENTIAL DONORS

a. The procedure for notifying the family of each potential donor of the patient's decision to donate or, as applicable under state law, the family's option to donate or decline to donate organs, tissue, or eyes, must state that this notification is to be made by the procurement organization coordinator or a trained designated requestor.

b. The following are certain elements which facilitate communication with the donor's family.

(1) Prior to approaching the family, the VA-designated requestor or liaison needs to review the patient's health record to determine whether the patient has expressed a preference regarding organ, tissue, and eye donation. If the patient has expressed a preference against donation, the family is not to be approached. If the patient has expressed a preference in favor of donation, this information must be shared with the family.

(2) The family must be given time to understand and accept their relative's death before the donation discussion. The medical staff needs to communicate often and honestly with the family regarding the patient's prognosis. The family needs to have a good understanding of the concept of brain death and cardiac death.

(3) In obtaining and determining consent for donation, VA staff must follow applicable state law. Irresolvable conflicts between a patient's donation decision and a family's wishes are to be referred to the facility Ethics Consultation Service or Regional Counsel.

(4) Any discussion regarding organ, tissue, or eye donation with the family needs to be held in a quiet, private setting. **NOTE:** *To ensure documentation of the processes is followed, a computerized template for the "Organ, Tissue and Eye Donation Certificate of Request" has been developed and is available to import into the local Computerized Patient Records System (CPRS). Health factors have been incorporated in the template to meet Joint Commission standards; this is available at: <http://vaww.va.gov/organdonation>. This is an internal web site and is not available to the public.*

11. PROTOCOL FOR PROCESSING DONATION REFERRALS

The protocol for processing donation referrals needs to include guidelines for working with the procurement organizations to improve the donor pool and maintain potential donors. This protocol needs to:

- a. Outline facility processes and procedures for ensuring that patients are given the opportunity to indicate their preferences regarding organ, tissue, and eye donation.
- b. Ensure the patient's preferences are documented and honored within the limits of the law or facility capacity.
- c. Identify the affiliated procurement organization.
- d. Outline process and procedures for ensuring procurement organization coordinators undergo background screening as required by subparagraph 9c.
- e. Describe the procedure used for notifying the procurement organization in a timely manner of a patient who has died, or whose death is imminent. Instances where notification to the procurement organization is not made must be documented. *NOTE: Documentation of death notification is best maintained in a location easily accessible for review.*
- f. Ensure a procedure for maintaining the records of potential donors.
- g. Address the facility staff's discretion and sensitivity to the circumstances, beliefs, and desires of the families of potential donors.
- h. Set out the guidelines used for working cooperatively with the procurement organization in reviewing death records to improve identification of potential donors, and to maintain potential donors while the necessary testing takes place.
- i. Specify that the family is not to be approached for donation if the patient has a preference documented in the health record against donation. Prior to approaching the family of a medically suitable candidate for donation, the VA designated requestor or liaison must review the patient's health record for any such documentation.
- j. Address staff education on medical chart reviews and on donation issues in cooperation with the procurement organization. This needs to clarify the roles and responsibilities for the both the facility and the procurement organization.
- k. Address the timeframe for procurement practices to ensure viable donation.
- l. Include a reference or a copy of the state's Uniform Anatomical Gift Act. All 50 states have established locally-accepted criteria (usually the Uniform Determination of Death Act) for determining the time of a patient's death. *NOTE: Regional Counsel needs to be contacted for the appropriate reference materials.*

12. REFERENCES

- a. Public Law 99-509, Omnibus Budget Reconciliation Act of 1986.
- b. The Social Security Act, 42 U.S.C. 601, et seq. and 42 U.S.C. 1320b-8.

c. Title 42 CFR 482.45 (Condition of participation: Organ, tissue, and eye procurement); 42 CFR 486.342 (Condition: Requesting consent).

d. Title 38 U.S.C. 5701(k)(1)(A) and 38 U.S.C. 7332(b)(2)(E).

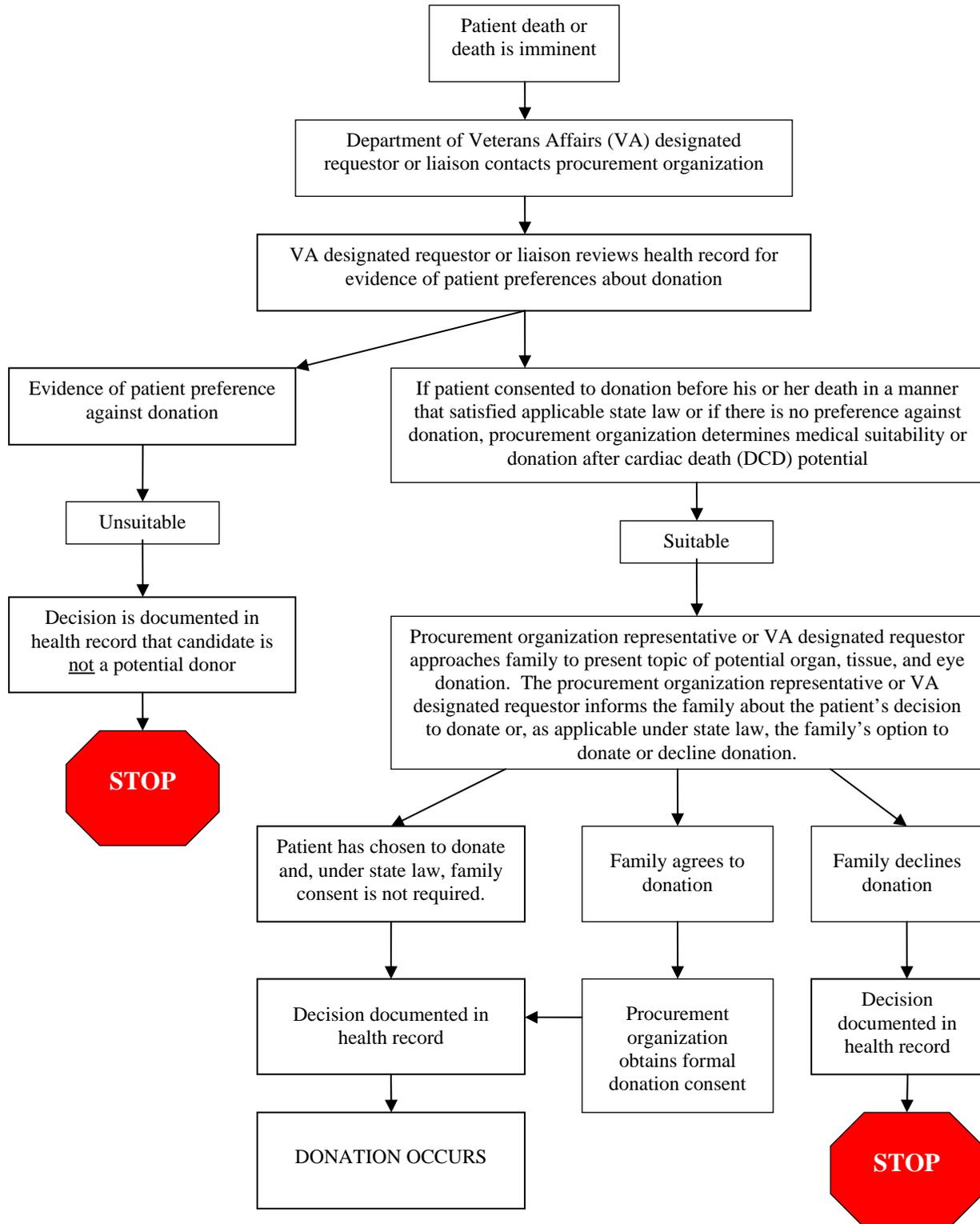
e. Joint Commission 2006 Comprehensive Accreditation Manual for Medical Centers, Standard TS.01.01.01 and TS.02.01.01, Standard RI.01.05.01, Standard PI.02.01.01.

f. DOD Directive Number 6465.3, Organ and Tissue Donation, May 4, 2004.
<http://www.dtic.mil/whs/directives/corres/pdf/646503p.pdf>.

g. VHA Handbook 1605.1.

h. Disclosure of Information to Organ, Tissue, and Eye Procurement Organizations, 73 Federal Register. 65258 (Nov 3, 2008) (to be codified at 38 CFR, Pt.1).

DEATH AND ORGAN, TISSUE, EYE DONATION FLOW CHART



REMINDER DIALOGUE TEMPLATE: TISSUE AND ORGAN DONATION

Following is a “screen capture” from the Computerized Patient Record System (CPRS) template developed which is available to import from: <http://vaww.va.gov/organdonation>. *NOTE: This is an internal web site and is not available to the public.*



Organ Donor
template.pdf