

ORGAN, TISSUE, AND EYE DONATION PROCESS

- 1. REASON FOR ISSUE:** This Veterans Health Administration (VHA) Handbook describes the procedures and requirements for processing referrals to local procurement organizations, which encompass solid organ, tissue, and eye donation.
- 2. SUMMARY OF MAJOR CHANGES:** This revision provides updates to the duties and responsibilities of VHA to establish and track agreements between Department of Veterans Affairs (VA) medical centers and organ procurement organizations, as well as eye and tissue banks.
- 3. RELATED ISSUES:** VHA Handbook 1102.07.
- 4. RESPONSIBLE OFFICE:** The National Surgery Office (10NC2) is responsible for the contents of this VHA Handbook. Questions may be referred to the VA National Surgery Office at 202-461-7130.
- 5. RESCISSIONS:** VHA Handbook 1101.03, dated April 30, 2009, is rescinded.
- 6. RECERTIFICATION:** This VHA Handbook is scheduled for recertification on or before the last working day of January, 2020.

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CONTENTS

ORGAN, TISSUE, AND EYE DONATION PROCESS

PARAGRAPH	PAGE
1. Purpose	1
2. Background	1
3. Definitions	2
4. Scope	3
5. Responsibilities	4
6. Agreements	6
7. Communicating with Family Members of Potential Donors	7
8. Protocol for Processing Donation Referrals	8
9. References	9

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. **AUTHORITY:** 38 U.S.C. 5701(k)(1)(A), 7301(b), and 7332(b)(2)(E), 21 CFR part 1271, 38 CFR 1.485a and 1.514b, and 42 CFR 482.45 and 486.342.

2. BACKGROUND:

a. The Omnibus Budget Reconciliation Act (OBRA) of 1986, sec. 9318, October 21, 1986, amended the Social Security Act to include several provisions relating to organ transplantation. Section 274 of Title 42 United States Code (U.S.C.) 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, VA voluntarily complies with the CMS regulation(s) to the extent possible under the law.

c. Federal regulations (Title 42 Code of Federal Regulations (CFR) 482.45 and 21 CFR part 1271) require medical centers to have and implement written protocols that, stated generally:

(1) Incorporate an agreement with a procurement organization.

(2) Contact the procurement organization and/or a designated third-party in a timely manner about individual deaths or individuals who are near death (imminent death).

(3) Collaborate with at least one tissue bank and one eye bank that are:

(a) Register with the Food and Drug Administration (FDA); and

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

(4) Ensure that the medical facility works with the designated procurement organization to inform:

(a) Families of patients about the patient's decision to donate his or her organs, tissue, and/or eyes (that was made in a manner that meets requirements of applicable state law); or

(b) In the absence of such a decision, the individual authorized under state law of that individual's right to make donation decisions.

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

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

(7) Ensure that the medical facility 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. VHA has authority under the Privacy Act, 5 U.S.C. 552a, the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, 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 procurement organizations for the purpose of determining individual suitability for organ, tissue, and/or eye donation. Per 45 CFR 164.512, a covered entity may use or disclose protected health information to organ procurement organizations or other entities engaged in the procurement, banking, or transplantation of cadaveric organs, eyes, or tissue for the purpose of facilitating organ, eye or tissue donation and transplantation.

e. VA medical centers must be in compliance with The 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 donation and procurement of organs, tissue, and/or eyes.

3. DEFINITIONS: For purposes of this Handbook, the following definitions apply:

a. **Agreement.** An agreement is defined as a document that a VA medical center develops in collaboration with a procurement organization (see paragraph 6). This agreement must detail the responsibilities and obligations of the parties with regard to identifying potential donors and facilitating the donation process.

b. **Death.** Consistent with applicable state law, death, or deceased, can be established by either neurological criteria (brain death) or circulatory criteria (circulatory death).

(1) **Brain death.** Brain death is defined as the irreversible cessation or loss of all function of the brain, including the brainstem. "Irreversible" means that function will not resume spontaneously and will not be restarted artificially.

(2) **Circulatory death.** Circulatory death is defined as the irreversible cessation of circulatory and respiratory function. "Irreversible" means that function will not resume spontaneously and will not be restarted artificially. The criteria applied by clinicians for determination of death are established by state law, and must include a documented absence of circulation, apnea, and lack of responsiveness to verbal and tactile stimuli.

c. **Donation after Circulatory Death.** Donation after Circulatory Death (DCD), also referred to as "Controlled DCD," is the voluntary decision of a patient (or an individual authorized by state law to make a donation decision on the patient's behalf) to donate the patient's organs following the death of the patient after voluntary removal of life-sustaining treatments.

d. **Near Death.** Near death refers to a situation in which the patient's health care provider has determined that the patient's death is imminent based on clinical judgment.

e. **VA Medical Center-Designated Requestor or Liaison.** The VA medical center-designated requestor or liaison is an identified staff member who assists the procurement organization. *NOTE: Designated requestors must complete a course offered and approved by the procurement organization that provides training in the methodology for approaching potential donor families.*

f. **VA Medical Center.** A VA medical center is a VA point of service that provides at least two categories of care (inpatient, outpatient, residential, or institutional extended care). (See VHA Handbook 1006.02, VHA Site Classifications and Definitions).

g. **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 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 42 U.S.C. 274 and 21 CFR Part 1271.

h. **Organ Procurement Organization Coordinator.** An OPO Coordinator is an OPO staff member who assists in donor management, suitability determination, and family services coordination. This individual facilitates the donation authorization process, coordinates the surgical procurement, and assumes immediate responsibility for the preservation and distribution of the organs to transplant centers according to guidelines established by United Network for Organ Sharing (UNOS). *NOTE: The OPO Coordinator does not participate in the clinical management of the potential donor.*

i. **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 is also an individual who consented to donation before his or her death in a manner that satisfied applicable state law requirements in the potential donor's state of residence. A patient who refuses donation or expresses a preference against donation does not qualify as a potential donor. Such refusal or preference by the patient needs to be documented and included in the patient's health record. When the record does not indicate any of the above situations and the patient is a suitable donor, then the individual responsible for making the donation decision under applicable state law is to be notified of his or her right to authorize, or refuse donation of, the patient's organ(s), tissue, and/or eyes.

4. SCOPE: It is VHA's goal that all VA medical centers enter into agreements with their local procurement organizations to identify potential donors in a manner consistent with applicable state law. Further, specific procedures must be developed in order for donation and procurement to be adequately documented and to proceed in accordance with the highest medical and ethical standards.

5. RESPONSIBILITIES:

a. **VHA National Director of Surgery.** The VHA National Director of Surgery shall monitor and track agreements between VA medical centers and procurement organizations.

b. **Veterans Integrated Service Network Director.** The Veterans Integrated Service Network (VISN) Director must ensure that each VA medical center within the VISN has entered into agreement(s) with procurement organization(s) in accordance with the requirements set forth in this Handbook.

c. **VA Medical Center Director.** The VA medical center Director is responsible for:

(1) Verifying that the VA medical center enters into an agreement with the appropriate procurement organization(s) to address donation procedures.

(2) Verifying in January of each calendar year (38 CFR 1.514b) with the Food and Drug Administration (FDA) that:

(a) Each Eye Bank and Tissue Bank with which the VA medical center has an agreement 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) Verifying that the VA medical center has provided all required information.

(4) Ensuring that 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, Privacy and Release of Information.

(5) Ensuring that the procurement organization is notified of all deaths, regardless of whether the VA medical center has full ventilator capability, ventilator capability only for patients who are to be transferred to a more complex medical facility, or no ventilator capability.

(6) Ensuring that the appropriate VA medical center staff works with the procurement organization 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 paragraph 6).

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

(8) Ensuring that a written procedure is in place for: a) notifying the family of each potential donor of the patient’s decision to donate, as requested; or b) in the absence of a donor document and/or patient decision to donate made in a manner consistent with applicable state law, notifying the appropriate person to authorize donation under applicable state law of their option

to donate or decline to donate organs, tissue, or eyes (see paragraph 7). **NOTE:** *The procurement organization should collaborate with medical center staff establishing this procedure.*

(9) Ensuring that written policies and procedures for donating and procuring organs and tissue are in place that:

(a) Meet the intent of Joint Commission Standard TS.01.01.01 and TS.02.01.01.

(b) Implement the policies and procedures set forth in this Handbook.

(c) Comply with Department of Defense (DoD) Directive 6465.3, May 4, 2004—Organ and Tissue Donation, or subsequent guidance provided by DoD for active duty service members receiving treatment in a VA medical center. **NOTE:** *A copy of DoD Directive 6465.3, can be located at: <http://www.dtic.mil/whs/directives/corres/pdf/646503p.pdf>.*

(10) Ensuring that 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 paragraph 8).

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

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

(b) 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, tissue, or eyes for donation.

(12) Ensuring that 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. For those VA medical centers without an operating room, the procurement organization may make arrangements for transfer of the donor to an appropriate medical facility.

(13) Ensuring that the procedure for notifying family members is effected in collaboration with the procurement organization (see paragraph 7).

(14) In any VA Transplant Center, in which any type of solid organ transplant is performed, the VA medical center 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 the Department of Health and Human Services.

d. **Medical Center Chief of Staff and the Associate Director of Patient Care Services/Nurse Executive.** The medical center Chief of Staff and the Associate Director of Patient Care Services (ADPCS)/Nurse Executive are responsible for:

- (1) Implementing, enforcing, and monitoring the protocol.
- (2) Identifying individual(s) to be responsible for notifying the procurement organization of a death or imminent death of a patient.
- (3) Identifying hospital staff to be the trained VA medical center-designated requestor or liaison.
- (4) Ensuring there is trained VA medical center-designated requestor or liaison coverage for all shifts.
- (5) Ensuring that the VA medical center staff are aware of the rights of the patient to make, or decline to make, organ, tissue, and/or eye donations (in a manner consistent with state law). Additionally, in the absence of the patient's decision, ensuring the proper identification of the appropriate person responsible under state law to authorize donation of the patient's organ(s), tissue, and /or eyes—or under DoD Directive 6465.3 in the case of active duty service members receiving treatment in VA medical facilities. (Consult with Regional Counsel, as needed, about the proper identification of such person under applicable state law.)

e. **VA Medical Center-Designated Requestor or Liaison.** As determined in the facility's agreement with the procurement organization, the VA medical center-designated requestor or liaison is responsible for:

- (1) Notifying the procurement organization, or third-party designated by the organ, tissue, or eye bank, of a patient's death or that a death is imminent. The liaison must make and document the call.
- (2) Collaborating in the donation authorization process with the procurement coordinator(s).
- (3) Ensuring procurement coordinator(s) have the information required to make donor suitability determinations.
- (4) Ensuring relevant electronic VA files are available for viewing by procurement coordinator(s).

f. **Medical Center Attending Physician.** The medical center attending physician, or designee, is responsible for notifying the VA medical center Director, the Chief of Staff, the ADPCS/Nurse Executive, and the Anesthesia staff (Anesthesiologist, Certified Registered Nurse Anesthetist) that organ, tissue, or eye donation is contemplated after death.

6. AGREEMENTS: Each VA medical center 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 medical center.* 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, Personnel Security and Suitability Program, VA Directive 6500, Managing Information Security Risk: VA Information Security Program, VA Handbook 6500, Risk Management Framework for VA Information Systems-Tier 3: VA Information Security Program, the Personal Identify Verification (PIV) Program, Federal Information Processing Standard (FIPS) 201, and the Federal Information Security Management Act (FIMSA) (see 44 U.S.C. 3541 through 3549).

7. COMMUNICATING WITH FAMILY MEMBERS OF POTENTIAL DONORS:

a. Local facility procedures must ensure that the family is notified of the patient's decision (recognized by state law) to donate his or her organs, tissue, or eyes. In the absence of such a decision, these procedures must ensure that the individual who is responsible to authorize donations under state law is notified of the individual's right to donate or decline to donate the patient's organs, tissue, or eyes. Such notification is to be made only by the procurement organization coordinator or a trained VA medical center-designated requestor or liaison.

b. The following are certain elements that facilitate communication with the donor's family and, if applicable, with the individual responsible for making the donation decision under state law.

(1) Prior to approaching the family, the VA medical center-designated requestor or liaison needs to review the patient's electronic health record to determine whether the patient has made a decision to donate his or her organs, tissue, and/or eyes and done so in a manner consistent with applicable state law. If so (and the decision was not subsequently revoked prior to brain death or circulatory death), then the patient's family is to be notified of the patient's decision to be a donor and of the fact that this decision will be honored. If the record shows that the patient refused donation, then the family is not to be approached about donation. If the patient did not make a decision to donate his or her organs, tissue, and/or eyes (that is recognized under applicable state law) but expressed a preference in favor of donation, this information must be shared with the family and, more specifically, with the individual authorized under state law to make the donation decision.

(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 circulatory death.

(3) With the exception of patients subject to the terms of DoD Directive 6465.3, May 4, 2004, when obtaining and determining authorization for donation, VA staff must follow applicable state law in all cases. Any disputes that arise are to be referred to Regional Counsel and decided under applicable state law.

(4) Any discussion regarding organ, tissue, or eye donation with the family needs to be held in a quiet, private setting.

8. 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 VA medical center 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 decision complies with applicable state law, or in the absence of such a decision, ensure the patient's preferences, are documented and honored in a manner consistent with applicable state law.

c. Identify the affiliated procurement organization.

d. Outline process and procedures for ensuring procurement organization coordinators undergo background screening as required by paragraph 6.c.

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 requirement for VA medical center staff discretion and sensitivity to the circumstances, beliefs, and desires of potential donors and their families.

h. Establish guidelines 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 prior to approaching the family of a medically suitable candidate for donation, the VA medical center-designated requestor or liaison must review the patient's health record for any documentation that the patient has either made a decision or indicated a preference against donation.

j. Specify that the family is not to be approached for donation if the patient has either made a decision or indicated a preference (documented in the health record) against donation.

k. 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 VA medical center and the procurement organization.

l. Address the timeframe for procurement practices to ensure viable donation.

m. Include a reference or a copy of the applicable state law(s) governing (cadaveric) donation of organs, eyes, and tissues. (Several states have done so by enacting or revising the Uniform Anatomical Gift Act.) Also include a copy of the applicable state law(s) and criteria that define the time of a patient's death. Regional Counsel must be contacted to obtain the appropriate legal reference materials. **NOTE:** *Many states have done so by adopting the Uniform Determination of Death Act.*

9. REFERENCES:

a. Public Law 99-509, Omnibus Budget Reconciliation Act of 1986, sec. 9318, October 21, 1986.

b. 42 U.S.C. 274.

c. 42 CFR 482.45 (Condition of participation: Organ, tissue, and eye procurement).

d. 42 CFR 486.342 (Condition: Requesting consent).

e. 38 U.S.C. 5701(k)(1)(A).

f. 38 U.S.C. 7332(b)(2)(E).

g. 45 CFR 164.512

h. Joint Commission, Standard TS.01.01.01 and TS.02.01.01, Standard RI.01.05.01, Standard PI.02.01.01.

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

j. VHA Handbook 1605.1, Privacy and Release of Information.

k. VHA Handbook 1102.07, Organ Donation After Circulatory Death (DCD).

l. 38 CFR 1.485a.

m. 38 CFR 1.514b.

n. 21 CFR part 1271.